Higher Nationals

MedTech for England

Specification

For use with the Higher National Certificate and Higher National Diploma in MedTech for England

First teaching from September 2026
First certification from 2027

Higher National Certificate Level 4

Higher National Diploma Level 5

Undergraduate Level Qualifications

Pearson BTEC

About Pearson

We are the world's leading learning company operating in countries all around the world. We provide content, assessment, and digital services to learners, educational institutions, employers, governments, and other partners globally. We are committed to helping equip learners with the skills they need to enhance their employability prospects and to succeed in the changing world of work. We believe that wherever learning flourishes, so do people.

References to third party materials made in this specification are made in good faith. Pearson does not endorse, approve or accept responsibility for the content of materials, which may be subject to change, or any opinions expressed therein. (Materials may include textbooks, journals, magazines and other publications and websites.)

All information in this specification is correct at time of publication.

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Contents

1.0 Introduction

BTEC is one of the world's most recognised applied learning brands, engaging students in practical, interpersonal and thinking skills for more than three decades.

BTECs are work-related qualifications for students taking their first steps into employment, or for those already in employment and seeking career development opportunities. BTECs provide progression into the workplace, either directly or via study at university, and are also designed to meet employers' needs. Therefore, Pearson BTEC Higher National qualifications are widely recognised by industry and higher education as the principal career-related qualification at Levels 4 and 5.

When developing our BTEC Higher National qualifications, we work with a wide range of students, employers, higher education providers, colleges and subject experts to make sure the qualifications meet their needs and expectations. We also work closely with professional organisations to make sure the qualifications are in line with recognised professional standards.

The Pearson BTEC Higher National qualifications are designed to reflect the increasing need for high-quality professional and technical education at undergraduate Levels 4 and 5. They provide students with a clear line of sight to employment and to a degree at Level 6 if they choose.

1.1 Qualifications indicated 'for England'

Qualifications that are indicated as 'for England' are designed to align to the requirements of specific occupational standards that meet the Institute for Apprenticeships and Technical Education's (IfATE) current occupation criteria. Meeting the requirements of the occupational standards relates to:

- qualifications that are 'quality marked' as Higher Technical Qualifications (HTQs)
- the knowledge, skills and behaviours for identified occupations associated with the relevant occupational standards.

1.2 Qualifications not indicated 'for England'

Qualifications that are **not** indicated as 'for England' can be delivered at any centre, in the UK or overseas, subject to approvals from Pearson. These qualifications are not 'quality marked' as HTQs by IfATE.

1.3 The student voice

Students are at the heart of what we do. That is why we consult them from the start when developing our Higher National qualifications. We involve them in writing groups, seek their feedback and take note of their opinions.

This helps us develop the best possible qualifications and learning experience for students worldwide.

1.4 Why choose Pearson BTEC Higher Nationals?

Pearson BTEC Higher National qualifications take a student-centred approach to the curriculum. There is a flexible, unit-based structure that focuses on developing the practical, interpersonal and thinking skills the student will need to succeed in employment and higher education. They represent the latest in professional standards and provide opportunities for students to develop skills and behaviours for work, for example by taking part in a group project or meeting a client brief. A student may be exempted from professional or vendor qualifications and membership of selected professional organisations, in order to help students on their journey to professional recognition or membership.

Pearson BTEC Higher Nationals are intended to keep doors open for future study if a student wishes to take their education further after completing a Higher National programme. They do this by allowing space for students to develop their higher education study skills, such as the ability to research. The study programme is clearly set out in line with the Quality Assurance Agency for Higher Education's Framework for Higher Education qualification standards at Levels 4 and 5. This means that students who want to progress to Levels 5 or 6 study should feel well prepared.

The Pearson BTEC Higher Nationals meet these requirements by providing:

- a range of general and specialist study units, both mandatory/core and optional, each with a clear purpose, so there is something to suit each student's choice of programme and future progression plans
- up-to-date content, closely in line with the needs of employers, professional bodies and higher education, for a skilled future workforce
- learning outcomes mapped against professional body standards, where appropriate
- support for tutors, including Authorised Assignment Briefs, curriculum planning support and assessment guidance, and
- support for students, including digital learning resources and communities, through HN Global.

1.5 HN Global

Our HN Global website provides a specially designed range of digital resources to give tutors and students the best possible experience during their BTEC Higher Nationals course. More information is available at: https://hnglobal.highernationals.com/.

1.6 Qualification titles

1.6.1 Pearson BTEC Level 4 Higher National Certificate in MedTech for England

Specialist pathways are included within brackets in the qualification title:

- Pearson BTEC Level 4 Higher National Certificate in MedTech for England.

1.6.2 Pearson BTEC Level 5 Higher National Diploma in MedTech for England

Specialist pathways are included within brackets in the qualification title:

- Pearson BTEC Level 5 Higher National Diploma in MedTech for England.

1.7 Qualification codes

Ofqual Regulated Qualifications Framework (RQF) qualification numbers:

- Pearson BTEC Level 4 Higher National Certificate in MedTech for England: **610/6104/9**
- Pearson BTEC Level 5 Higher National Diploma in MedTech for England: **610/6105/0.**

1.8 Awarding organisation

Pearson Education Ltd.

1.9 Key features

Pearson BTEC Higher National qualifications in MedTech for England offer the following:

- an exciting and informative study programme that stimulates and challenges students
- content that is closely aligned with occupational standards Level 4 Software Developer and Level 4 Associate Project Manager
- a simple and flexible structure that enables students to take the Higher National Certificate and then build on it in the Higher National Diploma, with optional units linked to their specialist area of study

- an opportunity for students to follow specialist routes of interest at Level 5, gaining the knowledge and skills they need to progress to higher education or employment in their specialist area
- core competencies developed throughout the curriculum, to support lifelong learning skills for personal and professional development
- the opportunity for centres to offer assessments that consider cognitive skills (what students know) along with effective and applied skills (how they behave and what they can do) to support a practical and dynamic approach to learning
- unit-specific assessment and Pearson-set themes designed to encourage thorough and analytical learning, challenge students and develop skills in critical thinking, personal responsibility and decision-making
- a flexible approach to assessment that supports progression to higher education or work and allows for different learning styles
- quality assurance measures that assure professional organisations, universities, businesses, colleges and students of the integrity and value of the qualifications, and
- a programme of learning designed to meet skills gaps in the current workforce and build today's talent to meet tomorrow's needs in an international environment.

1.10 Qualification frameworks

Pearson BTEC Higher National qualifications are recognised higher education qualifications in the UK. They are in line with the Framework for Higher Education Qualifications (FHEQ) in England, Wales and Northern Ireland, and Quality Assurance Agency (QAA) Subject Benchmark Statements, where applicable. These qualifications are part of the Regulated Qualifications Framework (RQF).

1.11 Collaborative development

We are very grateful to the university and further education tutors, employers, professional body representatives and other individuals who have generously shared their time and expertise to help us develop these new qualifications:

- 3P Innovation
- Aston University
- Aston Vision Sciences
- Birmingham Metropolitan University
- Black Country and Marches IoT
- Dignio Ltd
- Eventum Orthopaedics Ltd
- Hydrogel Healthcare Limited
- Linear Diagnostics Limited
- NHS
- Peili Vision Ltd
- PLMCS Ltd
- The Binding Site, part of Thermo Fisher Scientific
- TheComputingTutor Ltd
- West Midlands Combined Authority
- West Midlands Health Technologies Cluster.

2.0 Programming purpose and objectives

2.1 Purpose

The purpose of these qualifications is to develop students as independent-thinking professionals who can meet the demands of employers and adapt to a constantly changing world. The qualifications aim to widen access to higher education and improve the career prospects of those who take them.

2.2 Objectives

The objectives of these qualifications are:

- to develop the skills, knowledge and understanding that students need to achieve high performance in the MedTech environment
- to develop students with enquiring minds, who have the abilities and confidence to work across different MedTech functions and to lead, manage and respond to change, as well as tackle a range of complex MedTech situations
- to provide the core skills required for a range of careers in MedTech, including software and data engineering, medical device engineering, quality assurance management, regulatory affairs management, healthcare IT project management and technical sales and marketing
- to offer a balance between employability skills and the knowledge essential for students with entrepreneurial, employment or academic ambitions
- to develop students' understanding of the major impact that new digital technologies have on the MedTech environment
- to provide insight into MedTech operations and the opportunities and challenges presented by a global marketplace
- to equip students with knowledge and understanding of culturally diverse organisations, cross-cultural issues, diversity and values, and to allow flexible study to meet local and specialist needs.

2.3 Aims of the Level 4 Higher National Certificate in MedTech for England

The Level 4 units lay the foundations of learning by providing a broad introduction to MedTech. This develops and strengthens core skills while preparing students for specialist subjects at Level 5 or to enter employment with the qualities necessary for job roles that require some personal responsibility.

Students will gain a wide range of MedTech knowledge linked to practical skills gained through research, independent study, directed study and workplace scenarios.

Students are involved in vocational activities that help them to develop vocational behaviours (the attitudes and approaches required for competence) and transferable skills. Transferable skills are those such as communication, teamwork, research and analysis, which are highly valued in higher education and in the workplace.

By the end of Level 4, students will have sound knowledge of the basic concepts of medical technologies. They will be competent in a range of subject-specific skills as well as in general skills and qualities relevant to key areas of MedTech. The Level 4 units have been specifically designed to give students the opportunity to gain knowledge, skills and behaviours aligned to the Occupational Standard (OS) for Software Developer at Level 4.

2.4 Aims of the Level 5 Higher National Diploma in MedTech for England

The Level 5 units give students the opportunity to gain knowledge, skills and behaviours aligned to the Occupational Standards (OS) for Software Developer and Associate Project Manager. The units will prepare students to specialise in a MedTech-related occupational area and to progress to degree-level study. The units prepare students to move on to specific areas of MedTech at Level 6 or to enter employment with the qualities and abilities necessary for roles that require personal responsibility and decision-making.

Students will be able to develop and apply their own ideas to their studies, to deal with uncertainty and complexity, to explore solutions, demonstrate critical evaluation and use both theory and practice in a wide range of MedTech situations.

By the end of Level 5, students will have a sound understanding of the principles in medical technologies and will know how to apply those principles more widely in the MedTech sector.

2.5 Developing students' employability skills and academic study skills

Employability skills (sometimes referred to as transferable skills) are vital to increase students' career prospects and contribute to their personal development. Our BTEC Higher Nationals in MedTech for England support students in developing the key skills, qualities and strengths that employers are looking for.

We divide employability skills into five main categories.

Problem-solving skills

These include:

- critical thinking
- using expert and creative solutions to solve non-routine problems
- using systems and digital technology, and
- generating and communicating ideas creatively.

Independent skills

These include:

- self-management
- adaptability and resilience
- self-monitoring and self-development
- self-analysis, and
- reflection, planning and prioritising.

Interpersonal skills

These include:

- leadership skills
- communicating effectively
- working with others
- negotiating and influencing, and
- presentation skills.

Commercial skills

These include:

- awareness of the of the commercial aspects of the MedTech sector
- sales
- marketing, sales and promotion of MedTech products and inventions
- managing and monitoring budgets.

Business skills

These include:

- awareness of types of MedTech companies and governance structures
- ethical, social, legal and statutory responsibilities
- effective use of data and sector-related business management skills.

Students also benefit from opportunities for deeper learning, where they can make connections between different study units and select areas of interest for detailed study. In this way, the BTEC Higher National in MedTech for England provides a vocational context in which students can develop the knowledge and academic study skills they need to progress to university degree courses.

These academic study skills include:

- active research
- effective writing
- analytical skills
- critical thinking
- creative problem solving
- decision-making
- preparing for exams, and
- using digital technology.

Students can also develop their academic skills through independent study modules and resources on the HN Global website: https://hnglobal.highernationals.com/.

2.5.1 Use of maths and English within the curriculum

A career in MedTech requires both technical skills and broader employability skills. For example, appropriate communication with clients and colleagues is an essential skill, so the ability to use maths and English in a professional context is a key area for student development.

This type of development is embedded throughout BTEC Higher Nationals, in line with industry requirements. During their course, students may, for example, be involved in:

- preparing written reports
- giving formal presentations
- taking part in informal conversations
- using professional, sector-specific language.

Some aspects of MedTech require maths skills and we strongly recommend that all students complete diagnostic maths assessments before beginning a Higher National course, as well as having a grade 9 to 4 or A* to C in GCSE Maths. (See *Section 5.2* for more information.)

2.6 What could these qualifications lead to?

The Level 4 Higher National Certificate provides a solid grounding in MedTech, which students can build on if they decide to continue their studies. The Level 5 Higher National Diploma allows students to specialise by committing to specific career paths and progression routes to degree-level study.

Once students have achieved the Level 5 Higher National Diploma, they can develop their careers in the business sector by:

- entering employment
- continuing existing employment
- linking with the appropriate professional body
- linking with the appropriate vendor-accredited certificates (if appropriate)
- committing to Continuing Professional Development (CPD)
- progressing to university.

2.6.1 Progression to university

The Level 5 Higher National Diploma is recognised by higher education providers as meeting admission requirements to many relevant undergraduate MedTech-related courses, for example:

- BA/Sci (Hons) Applied Biomedical Science
- BA/Sci (Hons) Biomedical Informatics
- BA/Sci (Hons) Healthcare Science
- BA/Sci (Hons) Medical Innovation and Enterprise.

2.6.2 University recognition and articulations

We work with a range of higher education institutions around the world that accept Pearson BTEC Higher Nationals as a qualification for entry to their undergraduate degree courses. Many universities allow advanced entry to the second or third year of the course. Agreements can include transferring learning credits from one course or qualification to the other, articulation and case-by-case admission. An articulation agreement involves a university mapping the learning content of a Higher National against their degree programme(s). This process helps them understand how strong the alignment is between the Higher National and degree, and supports them in providing more guidance for students during the admissions process.

Students should be aware that each university sets its own admission criteria and that those criteria can change. Before applying, students should understand the course entry requirements for the subject and year in which they want to study. For more information on entry requirements, including 2+1 articulations, please visit: https://hnglobal.highernationals.com/degree-finder.

3.0 Preparing students for employment

3.1 Designing with employers, for employers

As a large employer and qualification-awarding organisation, Pearson understands the value of developing the skills and talent of the future workforce. We believe in, and champion, higher technical education that is relevant to employers.

We work with employers, students, professional bodies, education providers and other experts to design qualifications with the future workforce in mind. Higher National qualifications blend employability skills with academic, business and technical knowledge. They support trainees and apprentices in their Higher Apprenticeship and other technical education programmes, as well as students working towards a degree. We update our programmes regularly to maintain their high quality and meet the changing needs of the workforce.

Employers contribute to our Higher Nationals in several ways:

- They are involved in every stage of designing our qualifications, from developing the structure and pathways to selecting subjects, developing content and approving qualifications.
- They help us deliver qualifications, for example through vendor accreditation, letters of support and co-badging. Our qualifications actively encourage training providers to work with employers. Work placements and work-related learning are key features of BTEC Higher Nationals.
- They help us review and update our qualifications to meet occupational standards and provide supporting material such as case studies to reflect the real world of work.

We are committed to equipping apprentices, trainees and organisations with the tools and resources they need to support high-quality, innovative technical education and Higher Apprenticeship programmes that work.

Including a Higher National qualification as part of a Higher Apprenticeship or technical education programme gives students:

- an internationally recognised higher-level qualification in line with the Framework for Higher Education Qualifications, and
- a stepping-stone to continue their education or training and gain a recognised degree or professional qualification.

To find out more, and to access detailed mapping to higher apprenticeships and occupational standards for your qualification, please visit the following pages: https://qualifications.pearson.com/en/qualifications/apprenticeships.html and https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/higher-nationals/higher-technical-qualifications.html on our website.

3.1.1 Employability skills and competencies for student career success

Pearson is committed to delivering learning that is rooted in the real world and to developing work-ready graduates with the professional skills and behaviours that employers need. The Pearson BTEC Higher National curriculum provides a clear line of sight to employment, depending on which specialist areas students complete. The aim is to produce students who are equipped to thrive in the changing world of work, whether they leave with an HNC or an HND qualification.

The table below shows the type of position in which a student graduating at each educational level might expect to start and gives some examples of the competencies expected.

Table 1: Displaying levels of competency at employability level and examples of roles in different areas of MedTech at each level

Levels of competency			
Employability level at learning level	**Level 4 Operational**	**Level 5 Managerial**	**Level 6 Professional**
General employment outcomes for graduates at each level	Graduates can: • perform key medical technology tasks • understand regulatory requirements, quality standards and compliance processes, and • work effectively in clinical and medical technology industry environments.	Graduates can: • increase performance through strategic planning to meet MedTech aims and objectives, and • have an understanding of managing medical technologies functions to work effectively in lower- or middle-management positions.	Graduates can: • take the lead and direct others, and • manage change effectively in middle-management positions.
Examples of roles in different areas of medical technologies	Medical Device Technician Quality Control Associate Regulatory Affairs Assistant	Clinical Engineer Quality Assurance Manager Medical Technology Product Manager	Regulatory Affairs Specialist Medical Technology Project Manager Manager of Medical Technology Development

3.1.2 Developing competencies for the workplace

Core competencies developed on the specialist pathways of the programme will support students in preparing for a range of employment opportunities in their chosen sector. These core competencies collectively summarise the key capabilities that are important across the sector, covering areas of relevant expertise and technical skills that would be required within the sector to successfully perform a job, as defined in current advertised job vacancies.

Core competencies are developed on the programme within a balanced framework of cognitive (knowledge), affective (behaviours) and psychomotor (practical) learning outcomes to encourage a more vocational and practical approach to learning. These have been mapped to the knowledge, skills and behaviours (KSBs) for the Level 4 occupational standard for Software Developer and the Level 4 occupational standard for Associate Project Manager.

3.1.3 Types of professional body agreements for Higher Nationals in MedTech for England

There are a variety of agreements that we can have in place with professional organisations, although note that not all of these will apply to all qualifications.

- **Professional accreditation:** where a specific study programme prepares students to register for a professional qualification. In some cases, completing the Higher National Diploma may be enough for students to receive the professional qualification.
- **Membership:** where students are offered student membership while studying, or progression onto membership upon completion of their qualification.
- **Recognition:** where a professional organisation recognises the value of a Higher National in preparing students for the industry.
- **Exemption:** professional organisations may also offer exemptions from units on some of their qualifications. This means that students completing these Higher National units will have covered the material required for those professional body units and can claim exemption when studying for the professional body qualification.

For full accreditation and exemption details for this qualification, where applicable, please refer to the Progression Hub on HN Global: https://hnglobal.highernationals.com/progression-hub/memberships-certs or on the Industry Engagement page on our qualification page: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/higher-nationals/industry-engagement.html. We continue to work to update and add new agreements; therefore please refer to these online pages for the most up-to-date information.

3.1.4 Higher apprenticeships and occupational standards

The Pearson BTEC Higher Nationals in MedTech for England map to the following occupational standards:

- software developer
- associate project manager.

The programme structures set out in *Section 6* provide information about the units that are required to meet the knowledge, skills and behaviours defined within these occupational standards.

The Level 4 units specified within the programme structures provide the underpinning knowledge, skills and behaviours that support students to engage with the role defined within the occupational standards.

The core and specialist units, defined in Level 5, provide occupationally relevant knowledge, skills and behaviours that further prepare students for employment and progression associated with the occupational standard.

4.0 Centre support

You can access a wide range of resources and support to help you set up and deliver our Pearson BTEC Higher Nationals in MedTech for England with confidence.

4.1 Specification

This specification gives you details of the administration of the qualifications and information on the units included in them.

4.2 HN Global

HN Global is a dedicated online learning platform for all Pearson BTEC Higher National students and delivery centres. You can find various free resources to support staff in delivering a Pearson BTEC Higher National programme and to guide students on their learning journey. The HN Global Forum connects students and tutors, and provides the opportunity to discuss common themes and to share good practice. HN Global also provides access to the following:

The Learning Zone includes student study materials such as core textbooks, study skills modules, a 'Progression hub' featuring opportunities to develop employability skills, an e-library and subject materials.

The Tutor Resources section hosts a wealth of delivery materials, reading lists, blended learning resources, video guidance on assessment and professional development opportunities. Staff can also access the Quality Assurance (QA) Hub for templates and more centre support.

Short Courses provides support for curriculum planning, developing schemes of work and developing students' academic skills.

These are available from the HN Global website at: https://hnglobal.highernationals.com/.

4.3 Authorised Assignment Briefs

We provide a booklet of Authorised Assignment Briefs (AABs) for a sample of units. These AABs have been developed to support centres with their assessment strategy for the delivery of a sample of units, as well as providing guidance and inspiration for effective planning and design of future assignment briefs.

It is important to note:

1. AABs can be used by centres if they meet your specific requirements following internal verification. They have been written to assess students' knowledge, understanding and skills specifically relevant to the unit Learning Outcomes, but they have not been contextualised to meet local need and international diversity. If using an AAB, the assignment brief should still be internally marked and made available for standards verification.
2. AABs can be modified and customised to meet localisation.

The AABs offer a range of real and simulated assessment activities, for example group work to encourage cooperation and social skills or a solution-focused case study to develop cognitive skills. The assessment grids for each unit explain the specific requirements for assessing these skills.

All assignments must still be moderated in line with the internal verification process. These AABs along with further guidance can be found in the *Effective assignment design for the Higher Nationals in MedTech for England: Authorised Assignment Briefs* booklet available on HN Global at: https://hnglobal.highernationals.com/.

The tutor resources section on HN Global also offers a wide range of resources and guidance documents to help you plan and design assessments effectively.

4.4 Pearson English

Pearson provides a full range of support for English learning, including diagnostics, qualifications and learning resources. Please see: https://www.pearson.com/languages.

The Pearson Languages portal also offers a variety of digital resources. The portal encourages users to get involved, and improves teaching and results.

5.0 Planning your programme

5.1 Delivering Higher Nationals

As a large employer and qualification-awarding organisation, Pearson understands the value of developing the skills and talent of the future workforce. We believe in, and champion, higher technical education that is relevant to employers.

You play a central role in helping your students choose the right Pearson BTEC Higher National qualification.

Assess your students very carefully to make sure they take the right qualification and the right pathways and optional units. This will allow them to progress to the next stage in their learning or employment journey. You should also check the qualification structures and unit combinations carefully when giving students advice.

Make sure your students have access to a full range of information and advice to help them choose the right qualification and units. When students are recruited, you need to give them accurate information on the title and focus of the qualification they are studying for. Centres must provide a programme specification for approvals, but it is also essential that centres produce:

- a staff handbook to support full- and part-time members of your team, and
- a student handbook to guide students through the course requirements so they know what is expected of them and understand their rights.

You can find more information in the *BTEC Higher Nationals Centre Guide to Quality Assurance and Assessment* handbook, available to download on our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

5.1.1 Centre approval

We need to approve all centres before they can offer our qualifications. This is to make sure that centres are ready to assess students and that we can provide the support you need.

For more information about becoming a centre and gaining approval to run our qualifications, please see 'Centre/Qualification approvals' in the support section of our website at: https://support.pearson.com/uk/s/article/Centre-Qualification-Approvals.

5.1.2 Tutor knowledge

Pearson does not currently explicitly stipulate any qualification or experience requirements for staff involved in the delivery, assessment and internal verification of BTEC higher education qualifications. This is because it would not be practical to impose such stipulations to cover the very wide range of subject areas and field of experience that the BTEC higher education qualifications encompass.

However, it is expected that centres recruit all delivery, assessment and internal verification staff with integrity; and have robust staff recruitment processes in place. It is expected that staff hold a nationally recognised qualification at or above the level of the qualification being delivered and/or equivalent relevant experience.

You can find more information in the *BTEC Higher Nationals Centre Guide to Quality Assurance and Assessment* handbook, available to download on our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

5.1.3 Resources

As part of your centre approval, you will need to show that the right resources and workspaces are available to deliver Pearson BTEC Higher Nationals. Some units need specific resources. This is clearly explained in the unit descriptions, where appropriate.

5.1.4 Delivering learning

With our approval, you can deliver our Pearson BTEC Higher Nationals using a mixture of learning options that meet your students' needs. We recommend you offer full-time, part-time, blended learning and distance learning modes of delivery.

If you are delivering distance learning, please see the *Pearson distance learning and assessment policy* available to download at: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html.

5.1.5 Support from Pearson

For each programme with active registrations, we will provide an external examiner to help you plan and review assessments. You will also be able to access training events and support from a dedicated team of Pearson Higher National subject leads. Please see: https://qualifications.pearson.com/en/support/training-from-pearson-uk.html.

5.2 Entry requirements and admissions

Pearson does not set formal entry requirements for our qualifications but, as a centre, you are responsible for making sure that the students you recruit have a reasonable chance of success on the programme.

Students who have recently been in education are likely to need:

- a BTEC Level 3 qualification in Computing/Engineering/Applied Science
- a T Level in Digital Software Development/Digital Support and Security/Digital Data Analytics/Science
- a GCE Advanced Level profile that demonstrates strong performance in a relevant subject or adequate performance in more than one GCE subject. This profile is likely to be supported by GCSE grades at 9 to 4 or A* to C (or equivalent) in subjects such as maths and English
- other related Level 3 qualifications
- an Access to Higher Education Diploma from an approved further education institution
- relevant work experience, or
- an international equivalent to the above qualifications.

Our Recognition of Prior Learning policy means that students' previous learning and experience can be taken into account, and they may be awarded certain qualifications or units of a qualification based on that learning or experience. Please see *Section 9* for more information.

5.2.1 English language requirements

Pearson's mission is to help people make more of their lives through learning.

To assist centres to recruit students who have the skills to benefit from undertaking a Higher National programme of study, we are providing the following clarification regarding the English language **admission requirements** when offering places to applicants.

All centres delivering Pearson BTEC Higher National qualifications in English must ensure that each applicant can demonstrate their capability to learn and be assessed at the relevant level in English.

Students applying for a Pearson BTEC Higher National qualification that is **taught and assessed completely in English** will need a certain level of English language skills.

Before accepting students onto a programme, you must make sure that those who are non-native English speakers and who have not carried out their final two years of schooling in English can demonstrate ability at a standard equivalent to:

- Common European Framework of Reference (CEFR) Level **B2**
- Pearson Test of English (PTE) Academic **51**

- International English Language Testing System (IELTS) **5.5** (reading and writing must be at **5.5**).

Students who have completed a Pearson BTEC Higher National qualification delivered partly or completely in another language but assessed in English will need to demonstrate ability in English to the standard above, but at the **end** of the programme.

It is up to you to decide what proof of ability students will need to provide.

5.3 Access to study

This section focuses on the administration you will need to carry out when delivering our Pearson BTEC Higher National qualifications. It will be most relevant to quality controllers, Programme Leaders and examinations officers.

Our qualifications should:

- be available to everyone able to reach the required standards
- be free from any barriers that restrict access and progress, and
- provide equal opportunities for all those who want to access the qualifications.

For more information, please see our *Equity, diversity and inclusion in Pearson qualifications and related services policy*, available at: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html.

Please recruit with integrity when registering students to our Pearson BTEC Higher National programmes. You should:

- make sure that students applying have the information and advice they need about the qualification to be sure it meets their needs
- check each student's qualifications and experience to make sure they have the potential to achieve the qualification, and
- for students with disabilities and specific needs, consider the support available to them during teaching and assessment. For more guidance, please see *Section 5.6.2* on reasonable adjustments.

5.4 Student registration and entry

All students should be registered on the qualification they are studying and suitable arrangements need to be made for internal and external verification. For information on making registrations, please see the information manual available in the support section of our website at: https://qualifications.pearson.com/en/support/support-for-you/exam-officers-administrators/entries-information-manual.html?view=manual.

Students can be formally assessed only for a qualification on which they are registered. If a student changes the qualification they want to study for (for example if they decide to choose a different specialist pathway), you must transfer their registration to the new pathway. We cannot sample a student's work unless they are registered on the correct pathway.

5.5 Access to assessments

Assessments need to be managed carefully so that all students are treated fairly and that results and certificates are published without delay.

Our equity, diversity and inclusion policy requires that:

- all students have an equal opportunity to access our qualifications and assessments, and
- our qualifications are awarded in a way that is fair to every student.

We are committed to making sure that:

- students with a protected characteristic as defined by law (for example race, sexuality, religious belief) are not disadvantaged in comparison to students who do not share that characteristic
- all students achieve the recognition they deserve for taking a qualification, and this achievement can be compared fairly to the achievement of their peers.

For more information on access arrangements, please visit the Joint Council for Qualifications (JCQ) website at: https://www.jcq.org.uk/exams-office/access-arrangements-and-special-consideration/.

5.6 Administrative arrangements for internal assessment

5.6.1 Records

You are required to retain records of assessment for each student. Records should include assessments taken, decisions reached and any adjustments or appeals. Further information on quality and assessment can be found in our UK and international guides available in the support section on our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html. We may ask to audit your records, so they must be retained as specified. All student work must be retained for **a minimum of 12 weeks** after certification has taken place.

5.6.2 Reasonable adjustments to assessment

A reasonable adjustment is one that is made before a student takes an assessment, to ensure that they have fair access to demonstrate the requirements of the assessments.

You are able to make adjustments to internal assessments to take account of the needs of individual students. In most cases this can be achieved through a defined time extension or by adjusting the format of evidence. We can advise you if you are uncertain as to whether an adjustment is fair and reasonable. You need to plan for time to make adjustments, if necessary.

Further details on how to make adjustments for students with protected characteristics are available in the support section of our website: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html.

5.6.3 Special consideration

Special consideration is given after an assessment has taken place for students who have been affected by adverse circumstances, such as illness, and require an adjustment of grade to reflect normal level of attainment. You must operate special consideration in line with Pearson policy. You can provide special consideration related to the period of time given for evidence to be provided, or for the format of the assessment (if it is equally valid). You may not substitute alternative forms of evidence to that required in a unit, or omit the application of any assessment criteria to judge attainment. Pearson can consider applications for special consideration in line with the JCQ guide to the special consideration process, which can be downloaded from the JCQ website: https://www.jcq.org.uk/exams-office/access-arrangements-and-special-consideration/regulations-and-guidance/.

Please note that your centre must have a policy for dealing with mitigating circumstances if students are affected by adverse circumstances, such as illness, which result in non-submission or late submission of assessment.

5.6.4 Appeals against assessment

Your centre must have a policy for dealing with appeals from students. These appeals may relate to assessment decisions being incorrect or assessment not being conducted fairly. The first step in such a policy could be a consideration of the evidence by a Programme Leader or other member of the programme team. The assessment plan should allow time for potential appeals after assessment decisions have been given to students. If there is an appeal by a student, you must document the appeal and its resolution. Students have a final right of appeal to Pearson, but only if the procedures that you have put in place have been followed.

Further details of our policy on enquiries and appeals are available in the support section of our website: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html/ and can be downloaded from the JCQ website: https://www.jcq.org.uk/exams-office/access-arrangements-and-special-consideration/.

If your centre is located in England or Wales and the student is still dissatisfied with the final outcome of their appeal, they can make a further appeal to the Office of the Independent Adjudicator (OIA) by emailing: enquiries@oiahe.org.uk. In Northern Ireland a further appeal may be lodged with the Northern Ireland Public Service Ombudsman (NIPSO) by emailing: nipso@nipso.org.uk.

5.7 Dealing with malpractice in assessment

'Malpractice' refers to acts that undermine the integrity and validity of assessment, the certification of qualifications and/or may damage the authority of those responsible for delivering the assessment and certification.

Pearson does not tolerate actual or attempted actions of malpractice by learners, centre staff or centres in connection with Pearson qualifications. Pearson may impose penalties and/or sanctions on learners, centre staff or centres where malpractice or attempted malpractice has been proven.

Malpractice may occur or be suspected in relation to any unit or type of assessment within a qualification. For further details on malpractice and advice on preventing malpractice by learners, please see Pearson's *Centre guidance: dealing with malpractice and maladministration*, available to download on our website: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html.

Centres are required to take steps to prevent malpractice and to investigate instances of suspected malpractice. Learners must be given information that explains what malpractice is for internal assessment and how suspected incidents will be dealt with by the centre. The *Centre guidance: dealing with malpractice and maladministration* document gives full information on the actions we expect you to take.

Pearson may conduct investigations if we believe a centre is failing to conduct internal assessment according to our policies. The malpractice guidance document gives further information and examples, and details the penalties and sanctions that may be imposed.

In the interests of learners and centre staff, centres need to respond effectively and openly to all requests relating to an investigation into an incident of suspected malpractice.

5.7.1 Student malpractice

The Heads of Centres are required to report incidents of suspected student malpractice that occur during Pearson qualifications. We ask centres to complete a *JCQ Form M1* available to download at: www.jcq.org.uk/malpractice and email it with any accompanying documents (signed statements from the student and invigilator, copies of evidence etc.) to the Investigations Processing team at: candidatemalpractice@pearson.com. The responsibility for determining appropriate sanctions or penalties to be imposed on students lies with Pearson.

Students must be informed at the earliest opportunity of the specific allegation and the centre's malpractice policy, including the right of appeal. Students found guilty of malpractice may be disqualified from the qualification for which they have been entered with Pearson.

Failure to report malpractice constitutes staff or centre malpractice.

5.7.2 Tutor and centre malpractice

Heads of Centres are required to inform Pearson's Investigations Processing team of any incident of suspected malpractice (which includes maladministration) by centre staff, before any investigation is undertaken. The Heads of Centres are requested to inform the Iinvestigations team by submitting a *JCQ Form M2* (downloadable from: www.jcq.org.uk/malpractice) with supporting documentation to: pqsmalpractice@pearson.com. Where Pearson receives allegations of malpractice from other sources (for example Pearson staff, anonymous informants), the investigations team will conduct the investigation directly or may ask the Head of Centre to assist.

Pearson reserves the right in cases of suspected malpractice to withhold the issuing of results/certificates while an investigation is in progress. Depending on the outcome of the investigation, results and/or certificates may not be released or they may be withheld.

We reserve the right to withhold certification when undertaking investigations, audits and quality assurance processes. You will be notified within a reasonable period of time if this occurs.

5.7.3 Sanctions and appeals

Where malpractice is proven, we may impose sanctions or penalties, such as:

- mark reduction for affected external assessments
- disqualification from the qualification, or
- debarment from registration for Pearson qualifications for a period of time.

If we are concerned about your centre's quality procedures, we may impose sanctions such as:

- working with centres to create an improvement action plan
- requiring staff members to receive further training
- placing temporary suspensions on certification of students
- placing temporary suspensions on registration of students
- debarring staff members or the centre from delivering Pearson qualifications, or
- suspending or withdrawing centre approval status.

The centre will be notified if any of these apply.

Pearson has established procedures for considering appeals against penalties and sanctions arising from malpractice. Appeals against a decision made by Pearson will normally be accepted only from the Head of Centre (on behalf of students and/or members of staff) and from individual members (in respect of a decision taken against them personally). Further information on appeals can be found in the JCQ Appeals booklet available to download at: https://www.jcq.org.uk/exams-office/appeals.

6.0 Programme structure

6.1 Units, credits and Total Qualification Time (TQT)

The Higher National Certificate (HNC) is a Level 4 qualification made up of 120 credits. It is usually studied full time over one year, or part time over two years.

The Higher National Diploma (HND) is a Level 4 and Level 5 qualification made up of 240 credits. It is usually studied full time over two years, or part time over four years.

Pearson would expect an HND student to have achieved at least 90 credits at Level 4 before progressing to Level 5 units. This allows the student to submit the remaining 30 credits at Level 4 while continuing with their Level 5 study.

If an HND student does not complete the full qualification, they may be awarded an HNC if they have gained enough credits.

Pearson BTEC Higher Nationals consist of core units, specialist units and optional units.

- Core and specialist units are mandatory.
- Specialist units provide a specific occupational focus to the qualification, in line with professional body standards.
- Optional units provide greater depth and breadth of study and can be localised.

Each unit usually carries 15 credits. Units are designed around the amount of time it will take for a student to complete them and receive a qualification. This is known as the total qualification time (TQT). TQT includes guided learning activities, directed learning activities and assessment. Each 15-credit unit has a TQT of 150 hours – 60 guided learning hours (GLH) and 90 of independent learning hours (ILH). (For more information about guided and independent learning see *Sections 6.1.1* and *6.1.2*.)

- **The total qualification time for Higher National Certificate (HNC) = 1,200 hours.**
- **The total qualification time for Higher National Diploma (HND) = 2,400 hours.**

Examples of activities that can contribute to TQT include:

- guided learning
- independent and unsupervised research and learning
- unsupervised creation of a portfolio of work experience
- unsupervised e-learning
- unsupervised e-assessments
- unsupervised coursework
- watching a recorded podcast or webinar, and
- unsupervised work-based learning.

6.1.1 Guided learning hours

These are the hours where a tutor is present to give specific guidance towards the learning aim being studied. Guided learning hours include lectures, tutorials and supervised study in, for example, open learning centres and learning workshops. They also include supervised assessment activities such as invigilated exams, observed assessments and observed work-based practice.

- **The total guided learning hours for Higher National Certificate (HNC) = 480 hours.**
- **The total guided learning hours for Higher National Diploma (HND) = 960 hours.**

Examples of activities that can contribute to guided learning include:

- classroom-based learning supervised by a tutor
- work-based learning supervised by a tutor
- a live webinar or telephone tutorial with a tutor
- live e-learning supervised by a tutor, and
- all forms of assessment guided or supervised at the time by a tutor or other education or training provider. This includes where the assessment is competence based and turned into a learning opportunity.

6.1.2 Independent learning hours

These are the hours where a student is learning without the direct guidance of a member of centre staff. They are critical to the student's ability to develop knowledge and skills, as well as providing them with the opportunity to develop key transferable skills such as self-discipline, time management and self-motivation.

- **The total independent learning hours for Higher National Certificate (HNC) = 720 hours.**
- **The total independent learning hours for Higher National Diploma (HND) = 1,440 hours.**

Some examples of activities that can contribute to independent learning include:

- self-directed research and investigation
- reading set texts or other sources of information
- watching subject-related videos as part of investigation and research
- reviewing recordings of scheduled sessions or notes from those sessions
- peer activities, such as group meetings and online discussions, where students explore their learning together, and
- reviewing and recording thoughts on their own learning.

6.2 Programme structures

Programme structures specify the:

- total credit value of the qualification
- minimum credit to be achieved at the level of the qualification
- core units required
- specialist units required
- optional units available, and
- maximum credit value in units that can be centre-commissioned.

When combining units for our Pearson BTEC Higher National qualification, it is up to the centre to make sure that the correct combinations are followed.

6.2.1 Pearson BTEC Level 4 Higher National Certificate in MedTech for England

- Requires at least 120 credits, all at Level 4
- Total qualification time = 1,200 hours
- Total guided learning hours = 480 hours
- Mix of core, specialist and optional units, totalling 120 credits.

6.2.1.1 Pearson BTEC Level 4 Higher National Certificate in MedTech for England

Table 2: Structure for HN in MedTech for England at Level 4

Pearson BTEC Level 4 Higher National Certificate in MedTech for England			
Unit type	**Unit**	**Credits**	**Level**
Core *Mandatory*	Unit 401: Introduction to MedTech	15	4
Core *Mandatory*	Unit 402: Quality Management Systems (ISO 13485)	15	4
Core *Mandatory*	Unit 403: Risk Management (ISO 14971)	15	4
Core *Mandatory*	Unit 404: Applied Programming	15	4
Core *Mandatory*	Unit 405: Medical Devices	15	4
Core *Mandatory*	Unit 406: Regulatory Compliance	15	4
Core *Mandatory*	Unit 407: Software and UI/UX Design	15	4
Core *Mandatory*	Unit 408: Designing a MedTech Project Note: This is a Pearson-set unit.	15	4
Note 1: It is recommended to begin delivery with *Unit 1: Introduction to MedTech*, followed by *Unit 405: Medical Devices* and *Unit 406: Regulatory Compliance*.			

6.2.2 Pearson BTEC Level 5 Higher National Diploma in MedTech for England

- Requires 240 credits, of which 120 credits are at Level 5 and 120 credits are at Level 4.
- Total qualification time = 2,400 hours.
- Total guided learning hours = 960 hours.
- Mix of core, specialist and optional units, totalling 240 credits.
- Optional units are selected to make up the remaining credit value.
- Specialist units can also be selected as optional units for the general pathway and for any of the specialist pathways.

6.2.2.1 Pearson BTEC Level 5 Higher National Diploma in MedTech for England

Table 3: Structure for HN in MedTech for England at Level 5

Pearson BTEC Level 5 Higher National Diploma in MedTech for England			
Level 4 units			
Unit type	**Unit**	**Credits**	**Level**
Core *Mandatory*	Unit 401: Introduction to MedTech	15	4
Core *Mandatory*	Unit 402: Quality Management Systems (ISO 13485)	15	4
Core *Mandatory*	Unit 403: Risk Management (ISO 14971)	15	4
Core *Mandatory*	Unit 404: Applied Programming	15	4
Core *Mandatory*	Unit 405: Medical Devices	15	4
Core *Mandatory*	Unit 406: Regulatory Compliance	15	4
Core *Mandatory*	Unit 407: Software and UI/UX Design	15	4
Core *Mandatory*	Unit 408: Designing a MedTech Project Note: This is a Pearson-set unit.	15	4
Note 2: It is recommended to begin delivery with *Unit 1: Introduction to MedTech*, followed by *Unit 405: Medical Devices* and *Unit 406: Regulatory Compliance.*			

Level 5 units			
Unit type	**Unit**	**Credits**	**Level**
Core *Mandatory*	Unit 501: Data Management and Cybersecurity	15	5
Core *Mandatory*	Unit 502: Computer Systems Validation	15	5
Core *Mandatory*	Unit 503: Managing a MedTech Project Note: This is a Pearson-set unit.	15	5
Core *Mandatory*	Unit 504: Data Analytics	15	5
Core *Mandatory*	Unit 505: Manufacturing Processes	15	5
Core *Mandatory*	Unit 506: Understanding User Needs	15	5
Plus 30 credits from **2** Level 5 units selected from those listed in the table below.			

Level 5 optional units			
Optional unit	Unit 507: DevOps Engineering	15	5
Optional unit	Unit 508: Professional Development	15	5
Optional unit	Unit 509: ISO Standard Auditing for Medical Devices	15	5
Optional unit	Unit 510: Good Practices in MedTech	15	5
Optional unit	Unit 511: Hardware, Robotics and Autonomous Systems in MedTech	15	5
Optional unit	Unit 512: Marketing and Sales Approaches	15	5
Optional unit	Unit 513: Quality by Design	15	5
Optional unit	Unit 514: Emerging Trends and Technologies	15	5
Optional unit	Unit 515: Advanced Manufacturing	15	5
Optional unit	Unit 516: Work-Based Experience	15	5

6.3 Pearson-set units

Pearson-set units form part of the core units. Pearson will decide on a theme each year.

It is a formal requirement that you must:

- apply the theme to Level 4 and Level 5 units, and
- develop an assignment, to be internally assessed, to involve students in work related to the theme.

You will find support in the Pearson-set Assignment Guidance for the units, and the theme and topic release documentation, which will be provided for each level, on the HN Global website at: https://hnglobal.highernationals.com/.

The Pearson-set unit provides a common framework for centres to develop work that will allow us to:

- compare information across the sector, and
- identify and share best practice in higher education teaching and learning.

We will share the best practice results with all centres.

For more information about assessing Pearson-set units, please see *Section 7*.

6.4 Unit descriptor example

The unit descriptor is how we define the individual units of study that make up a Higher National qualification. Students will complete the units included in the programme that you offer at your centre.

You can use any of the unit descriptors listed in *Section 11.0*. We have described each part of the unit as follows:

Table 4: Unit descriptor description

Unit title	A general statement of what the unit will cover.
Unit code	The Ofqual unit reference number.
Unit type	There are three unit types: • core (mandatory to all pathways) • specialist (mandatory to specific pathways) • optional (available to most pathways).
Unit level	All our Pearson BTEC Higher National units are at Levels 4 or 5.
Credit value	The credit value relates to the total qualification time (TQT) and unit learning hours (ULH). It is easy to calculate: • 1 credit = 10 ULH • 15 credits = 150 ULH. To complete a Higher National Certificate or Higher National Diploma, students must achieve all of the credits required. Refer to *Section 7.5* in the programme specification.
Introduction	Some general notes on the unit: • setting the scene • stating the purpose and aim, and • outlining the topics to be learned and skills gained through the unit.
Learning Outcomes	These clearly explain what students will be able to do after completing the unit. There are usually four Learning Outcomes for each unit.
Essential Content	This section covers the content that students can expect to study as they work towards achieving their Learning Outcomes.
Learning Outcomes and Assessment Criteria	Tutors can refer to this table when grading assignments. The table connects the unit's Learning Outcomes with the student's work. Assignments can be graded at 'Pass' (P), 'Merit' (M) and 'Distinction' (D), depending on the quality of the student's work.
Recommended Resources	This section lists the resources that students should use to support their study for the unit. It includes books, journals and online material. The programme tutor may also suggest resources, particularly for local information. It may also contain delivery requirements, e.g. specific equipment, case study material and learning resources, depending on the subject.

6.4.1 Web resources – referencing

Some units have web resources as part of their Recommended Resources list. Hyperlinking to these resources directly can cause problems, as their locations and addresses may change. To avoid this problem, we only link to the main page of the website and signpost students and tutors to the section where the resource can be found. Thereby, we have referenced web resources as follows:

[1] A link to the main page of the website

[2] The title of the site

[3] The section of the website where the resource can be found

[4] The type of resource it is, for example:

- research
- general reference
- tutorials
- training
- e-books
- report
- wiki
- article
- datasets
- development tool
- discussion forum.

Example

[1] www.fda.gov/

[2] US Food & Drug Administration

[3] Reprocessing of Reusable Medical Devices

[4] (General reference)

Students and tutors must use a referencing system to cite and reference resources in an academic format.

7.0 Assessment

Pearson BTEC Higher Nationals are assessed using a combination of:

- centre-developed internal assignments that are set and assessed by centres, and
- Pearson-set assignments, which are set by centres in line with our guidelines and graded by centres.

Pearson-set units are mandatory and target particular industry-specific skills. The number and value of these units are dependent on qualification size. Furthermore:

- for the HNC, centres will assess one compulsory Pearson-set unit targeted at particular skills:
  - one Level 4 core unit carrying 15 credits
- for the HND, centres will assess two compulsory Pearson-set units targeted at particular skills:
  - one Level 4 core unit carrying 15 credits
  - one Level 5 core unit carrying 15 credits.

All other units are assessed through internal assignments set by the centre.

7.1 Principles of internal assessment

This section summarises the main features of internal assessment and explains how you can offer it effectively. Full details are given in the *BTEC Higher Nationals Centre Guide to Quality Assurance and Assessment* handbook, downloadable in the enhanced quality assurance section of our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html. All of your assessment team will need to refer to this document.

For Pearson BTEC Higher Nationals, you must meet the expectations of stakeholders and the needs of students by providing a programme that is practical and applied. You can tailor programmes to meet local needs and should use links with local employers and the wider business sector.

Effective internal assessment is challenging, engaging, practical and up to date. It must also be fair to all students and meet national standards.

7.1.1 Assessment through assignments

For internally assessed units, assessment takes the form of an assignment carried out after the unit (or part of the unit if several assignments are used) has been delivered. An assignment may take a variety of forms, including practical and written. It is a distinct activity completed independently by students (alone or in a team). It is

separate from teaching, practice, exploration and other activities that students complete with direction from tutors.

Students should receive each assignment as an assignment brief with a handout date, a completion date, and clear requirements for the evidence they must provide. There may also be specific practical activities which the student must complete under tutor observation as part of the assignment. Assignments can be divided into separate parts and may require several forms of evidence. A valid assignment will enable a clear and formal assessment grade based on the assessment criteria.

7.1.2 Using unit-based criteria

You must base your assessment decisions for Pearson BTEC Higher Nationals on the specific criteria we have provided for each unit and grade level. We have based these criteria on a framework to make sure that standards are consistent in the qualification and across the whole range of qualifications. We have developed each unit to assess the student's understanding, practical skills and the vocational qualities necessary for the qualification.

The assessment criteria for a unit are based on a hierarchy. For example, if a Merit criterion requires the student to show 'analyses' and the related Pass criterion requires the student to 'explain', then to gain a Merit the student will need to cover both 'explain' and 'analyses'. The unit assessment grid shows the relationships among the criteria so that Assessors can apply all the criteria to the student's evidence at the same time.

Assessors must show how they have reached their decisions using the criteria in the assessment records. When a student has completed all the assessments for a unit, the assessment team can give a grade for the unit. This grade is based on the highest level the student is judged to have met for all the criteria.

- To achieve a Pass, a student must have met all the Pass criteria for the Learning Outcomes, demonstrating that they have covered the unit content and achieved Level 4 or 5 of the national framework.
- To achieve a Merit, a student must have met all the Merit criteria (and the Pass criteria) through high performance in each Learning Outcome.
- To achieve a Distinction, a student must have met all the Distinction criteria (and the Pass and Merit criteria), demonstrating outstanding performance across the whole unit.

A Pass cannot be awarded just because the student has completed all the assignments. Students must meet all of the Pass criteria. If they do not, their grade should be reported as 'unclassified'.

7.1.3 The assessment team

You will need an effective team for internal assessment. There are three key roles involved, each with different responsibilities. These roles are listed below:

- The **Programme Leader** is responsible for the programme, its assessment and internal monitoring to meet our requirements. They must register with us each year. They are also responsible for:
  - record keeping
  - liaising with the standards verifier
  - acting as an Assessor
  - supporting the rest of the assessment team
  - making sure that the team has the information it needs about our assessment requirements
  - organising training, and
  - using our guidance and support materials.
- **Internal Verifiers** oversee all assessment activity with the Programme Leader. They check that assignments and assessment decisions are valid and meet our requirements. All Internal Verifiers will follow the same standards and procedures as instructed by your Programme Leader. Internal Verifiers are usually also Assessors, but they do not verify their own assessments.
- **Assessors** set assignments or use assignments to assess students to national standards. Before taking any assessment decisions, they are trained by the Programme Leader to all work to the same standards and procedures. They also work with the Programme Leader and Internal Verifiers to make sure the assessment is planned and carried out in line with our requirements.

Our external examiner will sample student work across your Assessors. They will also want to see evidence of how you have verified assignments and will assess your decisions.

Full information is provided in the *BTEC Higher Nationals Centre Guide to Quality Assurance and Assessment*, available in the enhanced quality assurance section of our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

7.1.4 Effective organisation

Internal assessment needs to be well organised so that you can track student progress and so that we can make sure your assessments are in line with national standards. It is particularly important that you manage the overall assignment programme and deadlines to make sure that all your students can complete their assignments on time.

When developing an overall plan for delivering and assessing your programme, you will need to consider:

- the order in which you deliver units
- whether delivery will take place over short or long periods of time, and
- when assessment can take place.

We support you in this through:

- assessment and feedback guidance documents available on HN Global, and
- training materials and sample templates for curriculum planning.

Please also see the *BTEC Higher Nationals Centre Guide to Quality Assurance and Assessment*, available in the enhanced quality assurance section of our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

7.1.5 Preparing students

You need to make sure that your students understand their responsibilities for assessment and the centre's arrangements. From induction onwards, you will want to make sure that students are motivated to work consistently and independently to achieve their qualifications. They need to understand:

- how assignments are used
- the importance of meeting assignment submission deadlines, and
- that all the work submitted for assessment must be their own.

To support them, you should provide a guide that explains:

- how you use assignments for assessment
- how assignments relate to the teaching programme
- how to use and reference source materials, including how to avoid plagiarism, and
- your centre's approach to assessments – for example, how students must submit assignments, what happens if they submit late work, and how they can request an extended deadline in special circumstances.

7.2 Formative assessment and feedback

7.2.1 Frequency and timing of formative assessment

Pearson does not define a minimum or maximum number of formative assessment points. However, students should have some formative assessment for each assignment, in order to provide them with an understanding of their progress and to identify areas for continued development.

Formative assessment that is too frequent can be detrimental to students' development. On the one hand, it will create an environment where students are working to produce *for* the formative assessment, rather than using the outcomes of formative assessment to support their learning and development towards the summative assessment. In addition, too much formative assessment risks becoming 'coaching' as students will have time to respond only to what has been indicated in formative feedback.

Therefore, the frequency of formative feedback should be considered carefully, as part of an overall curriculum plan, to occur at points where there is a clear benefit for the student in gaining further insight into their development and progress.

The timing of formative assessment should also be considered. Formative assessment that is too close to a summative assessment does not provide effective learning for the student. With limited time between formative and summative assessment there is less opportunity for the student to make effective use of the feedback from formative assessment to address any issues in the work towards summative assessment. Again, there is also a risk that the feedback from formative assessment becomes simply instructions (coaching) for the student.

Care should be taken to ensure that formative assessment takes place with sufficient time for the student to reflect upon the feedback from the formative assessment and make whatever adjustments they deem necessary to improve their future work or performance towards summative assessment.

It is important to recognise that formative assessment can, in some cases, be continuous, depending on the learning and teaching strategy that has been adopted for a unit or programme. For example, where students may be undertaking a large project, which they are working on throughout the semester/term, you may have regular tutorials (either group or individual) to review work-in-progress and provide students with feedback that helps them to understand their progress and development. In this context, the tutorials are a form of continuous formative assessment. The feedback from these tutorials still needs to avoid coaching and tutors should plan for tutorials (formative assessment) to stop at a point where there is sufficient time, before the summative assessment, to make effective use of the feedback in the later tutorials.

Please also see the *BTEC Higher Nationals Centre Guide in Quality Assurance and Assessment*, which can be found on our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

7.2.2 Formative feedback

While assessment and feedback always constitute a part of the student's learning, the purpose of assessment will vary, depending on when it is undertaken and the aim of the assessment activity.

Formative assessment feedback is given to students during the learning journey. This is to say that it relates to formative assessment that may be undertaken, at any point, prior to the summative assessment. Just as formative assessment is undertaken to support students to understand their progress, the associated feedback must be aimed at helping the student to recognise their current position and how to move forwards.

Formative assessment should always result in qualitative feedback, not a grade. When giving formative assessment feedback it is important to avoid giving students advice that directly informs the work that they may do for summative assessment. This is referred to as 'coaching' and is inappropriate. Feedback should provide students with general advice on how to progress in their studies, but should not tell them what to do. For example, a tutor might say:

'…your analysis of the research is not clear, you will need to look at the research more critically…'

rather than

'…what you should be writing is…'.

In the former, the tutor is supporting the student to understand their current progress and how to improve. While the latter is 'coaching' the student.

Formative assessment can be either formal or informal. We might schedule specific points where students present work for formative assessment. Such instances can be valuable opportunities for group discussion and peer assessment. In such cases, it is expected that students will receive written formative assessment feedback. In other instances, the formative assessment feedback may be during tutorials or classroom activities.

Please also see the *BTEC Higher Nationals Centre Guide in Quality Assurance and Assessment*, which can be found on our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

7.3 Making valid assessment decisions

7.3.1 Authentic student work

An Assessor must assess only student work that is authentic – in other words, the student's own independent work. Students must sign a declaration for each assessment to confirm that it is their own work. This declaration must confirm that:

- any evidence submitted for the assignment is the student's own, and
- the student understands that if this is not the case, they may face penalties for malpractice.

Assessors must make sure that evidence is authentic by setting valid assignments and supervising students during the assessment period. Assessors must also take care not to provide direct input, instructions or specific feedback that may influence the student's work and final grade.

You can use Pearson templates or your own templates to document authentication.

If your Assessor suspects that a student's evidence is not authentic, they must take action in line with our policies for malpractice. Please see *Section 5.7* for more information.

7.3.2 Making assessment decisions using criteria

Assessors must use our criteria to make assessment decisions. They can judge the evidence from a student using all the relevant criteria at the same time, but they must be satisfied that there is enough detailed evidence for each criterion required. For example, including a concluding section may not be enough evidence to meet the criterion requiring 'evaluation'.

Assessors should use the information and support available to help them reach their decisions. This includes:

- examples of moderated assessed work, and
- their Programme Leader and assessment team's experience.

7.3.3 Dealing with late assignments

For assessment to be fair, it is important that students are all assessed in the same way and that some students are not given an advantage by having extra time or the opportunity to learn from others. You should develop and publish your own regulations on late assignments and circumstances where you may agree to an extension.

Students must understand your policy on completing assignments by the deadlines you give them. You may agree to extend a deadline for a genuine reason, such as illness, in line with your centre policies. Please see *Section 5.6* for more information.

You can apply a penalty to assignments that are submitted late. To do this, you should:

- assess the assignment normally
- apply the penalty or cap to the grade awarded
- tell the student their uncapped grade to recognise the learning they have achieved and provide genuine assessment feedback
- record both the uncapped and capped grades, and
- have both grades verified by a suitable Assessment Board, taking into account any genuine reasons for the assignment being late.

Please also see the *BTEC Higher Nationals Centre Guide in Quality Assurance and Assessment*, which can be found on our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

7.3.4 Providing assessment decisions and feedback

Once your assessment team has completed the assessment process for an assignment, they will provide a formal assessment decision. This should be recorded formally and reported to the student. The information given to the student:

- must show the formal decision and how it has been reached, including how assessment criteria have been met
- may show why they have not demonstrated achievement against assessment criteria
- must not provide feedback on how to improve evidence, and
- may provide feedback on how to improve in the future.

7.3.5 The opportunity to resubmit an assignment

If a student's assignment does not pass after the first assessment, they must have the opportunity to resubmit the assignment for reassessment. In this case:

- students can have the assignment reassessed once only
- if coursework and project-based or portfolio-based assignments need to be reassessed, this will usually involve carrying out the original activity again
- for examinations, reassessment will involve completing a new activity
- the grade for a reassessed assignment will be capped at a Pass, and
- assignments already graded at a Pass or higher cannot be reassessed.

7.3.6 Repeat units

If a student fails to achieve a Pass for a unit following reassessment, your Assessment Board may agree that they can repeat the unit. In this case:

- the student must pay the unit fee and study the unit again, with full attendance, and
- the grade for the unit (if successfully completed) will be capped at a Pass.

Students can repeat a unit once only.

7.3.7 Assessment Boards

It is a formal Pearson requirement that centres hold an Assessment Board for all your Pearson BTEC Higher National programmes. The main purpose of an Assessment Board is to make recommendations on:

- the grades achieved by students on the units
- extenuating circumstances
- cases of cheating and plagiarism
- students progressing to the next stage of the programme
- the awards to be made to students, and
- students resubmitting assignments and repeating units.

Assessment Boards may also monitor academic standards. The main board meetings normally take place at the end of the session, but if your centre operates on a semester system there may be meetings at the end of the first semester. There may also be separate meetings to deal with referrals.

If you do not have an Assessment Board, our external examiner will discuss this with your quality nominee and Programme Leader. Assessment Board reports and minutes provide valuable evidence of your quality assurance processes.

7.4 Planning and record keeping

For internal processes to be effective, your assessment team needs to be well organised and keep effective records. We will work closely with you to make sure you are meeting national standards. This process gives stakeholders confidence in your assessment approach.

Your Programme Leader must have an assessment plan, produced as a spreadsheet. This plan should include:

- the time required to train the assessment team and make sure they are working to the same standards and procedures
- the time available for teaching and carrying out assessments, including when students may complete assessments and when quality assurance will take place

- the completion dates for different assignments
- who is acting as Internal Verifier for each assignment and the date by which the assignment needs to be verified
- a procedure for Internal Verifiers to sample Assessors' decisions that covers all assignments, Assessors and a range of students
- a process to assess and verify students' work so that they receive formal decisions quickly, and
- a system for scheduling resubmissions.

The Programme Leader must also keep records of all assessments carried out. The key records are:

- checking of assignment briefs
- student declarations
- Assessor decisions on assignments, with feedback given to students, and
- confirmation of assessment decisions.

Examples of records and more information are available in the *BTEC Higher Nationals Centre Guide to Quality Assurance and Assessment*, available in the enhanced quality assurance process section of our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.

7.5 Calculating the final qualification grade

7.5.1 Conditions for the award

7.5.1.1 Conditions for awarding our HNC

To achieve our Pearson BTEC Level 4 Higher National Certificate qualification, a student must have:

- completed units equivalent to 120 credits at Level 4, and
- achieved at least a Pass in 105 credits at Level 4.

7.5.1.2 Conditions for awarding our HND

To achieve our Pearson BTEC Level 5 Higher National Diploma qualification, a student must have:

- completed units equivalent to 120 credits at Level 5
- achieved at least a Pass in 105 credits at Level 5
- completed units equivalent to 120 credits at Level 4, and
- achieved at least a Pass in 105 credits at Level 4.

7.5.2 Compensation

7.5.2.1 Compensation for the HNC

Students who have attempted but not achieved a Pass in one of their Level 4 15-credit units can still be awarded an HNC as long as they have completed and passed the remaining units.

7.5.2.2 Compensation for the HND

Students who have attempted but not achieved a Pass in one of their Level 4 15-credit units and one of their Level 5 15-credit units can still be awarded an HND as long as they have completed and passed the remaining units at both levels as per the rules of combination of the required qualification.

7.5.3 Calculating the overall qualification grade

A student's overall qualification grade is based on their performance in all units. They are awarded a Pass, Merit or Distinction using the points gained through all 120 credits, at Level 4 for the HNC or Level 5 for the HND. The overall qualification grade is calculated in the same way for the HNC and the HND. For HND, the overall qualification grade is based on student performance in Level 5 units only.

Students must have attempted all units in a valid combination for each qualification. The conditions of award and compensation arrangements will apply as explained above. If a student has been granted compensation for a unit attempted but not achieved, that unit will appear as unclassified (a 'U' grade) on the notification of performance provided with their certificate.

7.5.3.1 Points per credit

Table 5: Displaying points per credit

Grade	Points
Pass	4
Merit	6
Distinction	8

7.5.3.2 Point boundaries

Table 6: Displaying grade point boundaries

Grade	Point boundaries
Pass	420–599
Merit	600–839
Distinction	840+

7.5.4 Modelled student outcomes

7.5.4.1 Pearson BTEC Level 4 Higher National Certificate

Table 7: Displaying example model outcomes

	Credits	Level	Student 1			Student 2		Student 3		Student 4		Student 5	
			Grade point	Grade	Unit points	Grade	Unit points	Grade	Unit points	Grade	Unit points	Grade	Unit points
Core 1	15	4	4	P	60	P	60	P	60	D	120	D	120
Core 2	15	4	4	P	60	P	60	P	60	D	120	M	90
Core 3	15	4	4	P	60	P	60	P	60	D	120	M	90
Core 4	15	4	4	P	60	P	60	M	90	M	90	M	90
Core 5	15	4	6	M	90	P	60	M	90	M	90	M	90
Core 6	15	4	6	M	90	P	60	M	90	M	90	M	90
Core 7	15	4	6	M	90	M	90	D	120	D	120	D	120
Core 8	15	4	6	M	90	M	90	D	120	D	120	D	120
Total	120	–	–	–	600	–	540	–	690	–	870	–	810
Grade	–	–	–	–	M	–	P	–	M	–	D	–	M

7.5.4.2 Pearson BTEC Level 5 Higher National Diploma

Table 8: Displaying example model outcomes

	Credits	Level	Student 1			Student 2		Student 3		Student 4		Student 5	
			Grade point	Grade	Unit points	Grade	Unit points	Grade	Unit points	Grade	Unit points	Grade	Unit points
Core 1	15	4	0	P	0	P	0	P	0	D	0	P	0
Core 2	15	4	0	P	0	P	0	P	0	D	0	M	0
Core 3	15	4	0	P	0	P	0	P	0	D	0	M	0
Core 4	15	4	0	P	0	P	0	M	0	M	0	M	0
Core 5	15	4	0	M	0	P	0	M	0	M	0	P	0
Core 6	15	4	0	M	0	P	0	M	0	D	0	U	0
Core 7	15	4	0	M	0	P	0	D	0	D	0	D	0
Core 8	15	4	0	M	0	P	0	D	0	D	0	D	0
Core 9	15	5	6	M	180	M	180	M	180	P	120	D	240
Core 10	15	5	6	M	90	M	90	M	90	P	60	D	120
Core 11	15	5	6	M	90	M	90	D	120	P	60	D	120
Core 12	15	5	6	M	90	P	60	D	120	P	60	D	120
Core 13	15	5	6	M	90	P	60	D	120	P	60	M	90
Core 14	15	5	6	M	90	P	60	M	90	M	90	P	60
Optional 15	15	5	6	M	90	P	60	M	90	M	90	M	90
Optional 16	15	5	6	M	90	P	60	M	90	M	90	M	90
Total	240	–	–	–	810	–	660	–	900	–	630	–	930
Grade	–	–	–	–	M	–	M	–	D	–	P	–	D

The tables above are provided as general examples of using unit grades to calculate qualification grades. They do not reflect the specifics of this qualification.

8.0 Quality assurance

The quality assurance system for all Pearson BTEC Higher National programmes is linked to Level 4 and Level 5 of the Quality Assurance Agency (QAA) Framework for Higher Education Qualifications (FHEQ). This means that centres must have effective quality assurance processes to review their programme delivery. It also ensures that assessment grades are in line with national standards.

The quality assurance process for centres offering our Pearson BTEC Higher National programmes has five main features:

1. The approval process.
2. Monitoring internal systems.
3. Independent review of assessments.
4. Annual programme monitoring report.
5. Annual student survey.

8.1 The approval process

If you want to deliver our programmes at your centre, you must apply first through the existing centre approval process and then through the programme approval process. We can consider your application by:

- carrying out a desk-based review, or
- visiting your centre.

You will need to provide evidence that your centre:

- has the human and physical resources needed to deliver and assess the programme effectively
- understands the rules of independent assessment and agrees to follow them
- has a strong internal assessment system supported by 'fit for purpose' assessment documentation, and
- has a system to internally verify assessment decisions so that they are consistent across all Assessors and sites.

Your application must be supported by the Head of the Centre (your principal or chief executive). It must include a declaration that you will operate the programmes strictly and in line with our requirements.

If your centre is already approved and you want to renew approval, you may be able to use our automatic approval process.

We may withdraw qualification or centre approval if we believe you can no longer quality assure your programme delivery or assessment standards.

8.2 Centre and qualification approval

As part of the approval process, your centre must meet the conditions listed below before offering the qualification:

- you must have suitable physical resources (for example equipment, IT, learning materials, teaching rooms) to support delivery and assessment of the qualifications
- you must provide the specific resources required for individual units
- staff involved in the assessment process must have relevant skills or experience
- you must have systems to provide continuing professional development for staff delivering the qualification
- you must have suitable Health and Safety policies for students and staff using equipment, and
- you must deliver the qualification in line with current equality legislation.

In this way, we can provide qualifications that meet the needs and expectations of students worldwide.

8.3 Monitoring internal systems

You will need to demonstrate that you continue to meet our centre approval criteria over time and across all Higher National programmes. This involves providing evidence to our external examiners for review.

Our examiners will check that:

- your systems and the way you use them remain suitable for supporting the programmes
- you apply student registration and appeals policies consistently, and
- you have effective internal examination and standardisation processes.

In some cases, you may present evidence of your operation within a recognised code of practice, such as that of the Quality Assurance Agency for Higher Education. However, we may still want to confirm independently that these arrangements are operating to our standards.

If our examiners identify problems with your internal systems, we will take steps to help you correct them.

8.4 Independent review of assessments

The external examiner will review your internal assessments for all Pearson BTEC Higher National programmes benchmarked to Levels 4 and 5 of the Quality Assurance Agency (QAA) Framework for Higher Education Qualifications. They will either:

- confirm that your internal assessments meet national standards and allow certification, or
- provide actions to improve the quality of your assessments before allowing certification.

8.5 Annual programme monitoring report (APMR)

This annual review form gives you the opportunity to analyse and reflect on the most recent teaching year. It also provides us with information to help us improve the quality assurance of the Pearson BTEC Higher National programmes. An overview report is produced to outline the findings of the APMR each year.

8.6 Annual student survey

Pearson will conduct an annual survey of Pearson BTEC Higher National students. This provides us with a snapshot of every Higher National student's experience as part of the quality assurance process. Each centre with enough students taking part in the survey will get its own report about their results. You can access the report on HN Global at: http://hnglobal.highernationals.com.

8.7 Continuing quality assurance and standards verification

Each year we update our *BTEC Higher Nationals Centre Guide to Quality Assurance and Assessment*, available in the enhanced quality assurance section of our website: https://qualifications.pearson.com/en/qualifications/btec-higher-nationals/about/quality-assurance-process.html.
The handbook contains detailed guidance on the quality processes you should follow.

8.7.1 Our key principles of quality assurance

- A centre delivering Pearson BTEC Higher National programmes must be approved by us and must have our approval for the programmes or groups of programmes it is delivering.
- As part of gaining our approval, the centre agrees always to follow our terms and conditions for delivering programmes effectively and assessment quality assurance.

- We provide approved centres with a range of materials and opportunities for reviewing internal materials through our assessment-checking service. This service demonstrates the processes required for effective assessment and provides examples of effective standards. You must use these materials and services to make sure that all staff delivering Pearson BTEC Higher National qualifications keep up to date with the guidance on assessment.
- You must follow agreed processes for:
    - planning, monitoring and recording assessment processes, and dealing with special circumstances, appeals and malpractice, and
    - making sure that Assessors and verifiers all work to the same standards.
- We will work in partnership with you to help you achieve quality assured assessment.
- We will help you follow best practice and use suitable technology to support quality assurance processes.
- We will try to make sure our quality assurance processes do not create unnecessary administrative work for you.
- We will monitor and support you in achieving effective assessment and quality assurance.

We will do this by:

- making sure that you complete a suitable declaration at the time of approval
- carrying out approval visits to your centre
- making sure that you have a well-trained, effective team of Assessors and verifiers
- sampling and verifying your assessments, assessed student work and other relevant documents, and
- reviewing your strategy for assessing and quality assuring your BTEC programmes.

As an approved centre, you must advertise your certification only with our permission and in line with our reporting requirements.

If you do not have and maintain a strong approach to quality assurance, you will not be able to apply for certification for any Pearson BTEC Higher National qualifications.

If you do not follow our recommendations for improving your quality assurance, we may withdraw approval for you to deliver our qualifications.

8.8 Use of Higher Technical Qualifications (HTQ) quality mark

When delivering the BTEC Higher Nationals in MedTech for England, centres must take care to ensure that they use the HTQ quality mark with due care and attention on promotional material.

The quality mark must be only used by centres in relation to an approved Higher Technical Qualification to demonstrate that the qualification has been:

- approved by the Institute for Apprenticeships and Technical Education (IfATE), and to advertise a specific course leading to a Higher Technical Qualification
- for careers advisory purposes, to explain and promote the Higher Technical Qualifications programme as a whole.

It should be used only to promote approved Higher Technical Qualifications and must not be used in a way that could reasonably be misinterpreted as a wider endorsement of any other qualifications or your centre overall.

For more information about who can use the quality mark and how it should be used, please refer to *The Higher Technical Qualification Quality Mark Guidelines* at: https://www.gov.uk/guidance/higher-technical-education-reforms.

9.0 Recognition of Prior Learning and attainment

Recognition of Prior Learning (RPL) is a way of awarding credit if a student can demonstrate they meet the assessment requirements for a unit through knowledge, understanding or skills they already have. As long as the assessment requirements are met, RPL can be used to accredit a unit, units or a whole qualification.

RPL provides a route for recognising the achievements of continuous learning from a range of activities using any valid assessment procedure. We encourage you to recognise students' previous achievements and experiences at work, at home, in leisure and in the classroom. Evidence of learning must be valid and reliable.

For full guidance on RPL, please see *Recognition of prior learning policy and process*, which can be downloaded from the support section of our website: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html.

10.0 Equality, diversity and inclusion

Equality and fairness are central to our work. The design of these qualifications embeds equality, diversity and inclusion as set out in the qualification regulators' general conditions of recognition.

Promoting equality and diversity involves:

- treating everyone with equal dignity and worth, and
- raising ambitions and supporting achievement for people with different needs and backgrounds.

Creating an inclusive learning environment means anticipating students' varying needs and trying to make sure that all students have equal access to educational opportunities. This involves providing access for people who have differing individual needs and removing unnecessary barriers to learning. Qualification design must be inclusive so that students with and without disabilities have equal access to learning opportunities.

Our equality, diversity and inclusion policy requires that:

- all students have an equal opportunity to access our qualifications and assessments
- assessments should reflect the wide diversity of students, and
- our qualifications are designed and awarded in a way that is fair to every student.

We are committed to making sure that:

- students with a protected characteristic as defined by law (for example race, sexuality, religious belief) are not disadvantaged in comparison with students who do not share that characteristic
- all students achieve the recognition they deserve for taking a qualification, and
- this achievement can be compared fairly to the achievement of their peers.

Our qualifications should:

- be available to everyone capable of reaching the required standards
- be free from any barriers that restrict access and progress, and
- offer equal opportunities for all those who want to access them.

Please see our *Equity, diversity and inclusion in Pearson qualifications and related services policy* downloadable from the support section of our website: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html.

Please use your integrity when recruiting students to our Pearson BTEC Higher National programmes. You should:

- make sure they have the information and advice they need about the qualification to be sure that it meets their needs
- check each student's qualifications and experience to make sure they have the potential to achieve the qualification, and
- for students with disabilities and specific needs, consider the support available to them and any other support they may need during teaching and assessment.

Please see our policy documents on students with particular needs.

10.1 Access to qualifications for students with disabilities or specific needs

Students can be assessed in a recognised regional sign language.

Further information on access arrangements can be found in the Joint Council for Qualifications (JCQ) at: https://www.jcq.org.uk/exams-office/access-arrangements-and-special-consideration and *A guide to the special consideration process − General and Vocational Qualifications* downloadable at: https://www.jcq.org.uk/exams-office/access-arrangements-and-special-consideration/regulations-and-guidance. Details on how to make adjustments for students with protected characteristics are provided in *Supplementary Guidance for Reasonable Adjustment and Special Consideration in Vocational Internally Assessed Units*. See the support section of our website for both documents: https://qualifications.pearson.com/en/support/support-topics/understanding-our-qualifications/policies-for-centres-learners-and-employees.html.

11.0 Units included in the BTEC Higher Nationals in MedTech for England

Unit 401: Introduction to MedTech

Unit code: J/651/7093

Unit level: 4

Credit value: 15

Introduction

Advancements in medical technology, known as MedTech, have helped revolutionise healthcare by enhancing diagnostic accuracy, treatment efficacy and patient outcomes. This unit provides a general introduction to the MedTech industry, examining the sector as a whole, the contributions of science and engineering to medical device development, as well as an overview of the progression opportunities available to anyone wishing to enter the industry. It provides a basic understanding of the core concepts, terminologies and key developments that form the backbone of modern medical technology.

The primary aim of this unit is to offer students a comprehensive overview of the MedTech sector, from the fundamentals of medical technology to contemporary applications and future potential. By exploring the significant scientific and engineering breakthroughs that have driven MedTech advancements, students will gain an appreciation of the field's evolution and its impact on healthcare. By reviewing both the theory and real-world practical examples, the unit guides students through the complexities of MedTech design, manufacture and utilisation.

The unit covers a wide range of topics central to understanding and innovating in MedTech. Key areas of focus include how modern electronic and bioengineering innovations have contributed to the development of medical technology, as well as the various progression pathways within the sector. The unit addresses the classifications and regulatory frameworks governing medical devices, Software as a Medical Device (SaMD), and the ethical considerations in data management and usage within the industry. Each topic is designed to create a detailed understanding, enabling students to grasp the complex nature of MedTech.

On successful completion of this unit, students will have developed analytical skills as well as technical and regulatory knowledge related to the MedTech industry. They will be able to explain key terms and concepts, explore the impact of medical technology on healthcare, and understand data management regulations. In addition, students will have a clear idea of the various career entry points within the sector, and where such a career might lead. These skills are directly linked to employment opportunities in various roles, such as MedTech Product Designer, Regulatory Affairs Specialist, Biomedical Engineer and Data Management professional.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Review the MedTech sector and the progression opportunities within it

LO2 Explain the key terms, concepts and categories in MedTech design, manufacture and utilisation

LO3 Explore the impact of medical technology on clinical and preventive healthcare settings

LO4 Review the data management regulations and requirements in the MedTech industry.

Essential Content

LO1 **Review the MedTech sector and the progression opportunities within it**

Overview of MedTech:

Medical device classification: e.g. Class I, IIa, IIb, III – risk-based categorisation

Software as a Medical Device (SaMD): e.g. AI-driven software, diagnostic tools, digital therapeutics

Regulatory frameworks: e.g. MDR, IVDR, FDA, MHRA

Sector growth: e.g. market expansion, technological advancements, investment trends, innovation adoption, regulatory changes

Stakeholders: e.g. healthcare providers, medical device manufacturers, regulatory agencies, investors and venture capitalists, patients and consumers

Business context: e.g. competitive landscape, business models (e.g. direct-to-consumer, subscription services, licensing and partnerships), mergers and acquisitions, funding and financing, distribution channels

Sector culture: e.g. innovation focus, ethical considerations, collaboration and partnerships, patient-centric approach, continuous learning.

Science and engineering contributions to medical technology advancements:

e.g. Discovery of X-rays – enabled non-invasive internal imaging
e.g. Development of transistor, 1947, Bell Labs – portable electronic medical devices, miniaturisation and better energy efficiency
e.g. Polypropylene synthesis: biocompatible surgical mesh, low weight, high strength for implants
e.g. Integrated circuit: advanced medical diagnostics and monitoring equipment,
e.g. increased computational power in smaller devices
e.g. DNA double helix: genetic testing and personalised medicine,
e.g. understanding of genetic diseases and tailored treatments
e.g. MRI: high-resolution, non-invasive imaging
e.g. Polymerase chain reaction (PCR): DNA amplification for testing, rapid, accurate genetic/viral testing, DNA sequencing
e.g. Nanotechnology: targeted drug delivery systems, precision in treatment, fewer side effects
e.g. Microprocessor: smart medical devices, wearable technology
e.g. Human genome project: e.g. genomic medicine, gene therapies, comprehensive genetic information for diagnostics/treatment
e.g. CRISPR gene editing: e.g. genome editing technologies, potential for curing genetic disorders.

Progression opportunities in MedTech

Certifications and training: e.g. ISO 13485 Auditor, ISO 14971 Auditor, Lean Six Sigma, IEEE 2621, Certified Quality Engineer (CQE)

Business skills development: e.g. skill enhancement, industry knowledge, networking opportunities, mentorship programmes

Career progression: e.g. leadership roles, cross-sector mobility, entrepreneurial ventures, international opportunities

Specialisation areas: e.g. biomedical engineering, robotics, advanced diagnostics, regenerative medicine, health informatics, diagnostic imaging, wearable medical devices, telehealth solutions, genetic testing, surgical innovation, personalised medicine, remote patient monitoring, cardiovascular technologies, nano-medicine.

LO2 **Explain the key terms, concepts and categories in MedTech design, manufacture and utilisation**

Categories of medical devices:

Pillars of use: definition, origins, meaning

Imaging devices: e.g. radiology, ultrasound, X-ray, MRI, CT scans, ultrasound, PET scans; AI-powered image analysis, contrast agents, fluoroscopy

Endoscopy and minimally invasive devices: e.g. endoscopic cameras, robotic-assisted endoscopy, laparoscopy; capsule endoscopy

Pathology and laboratory diagnostics: e.g. in vitro diagnostics (IVD), lateral flow tests, automated laboratory instruments; PCR testing, haematology analysers, cell imaging systems; microscopy (including optical, transmission electron and scanning electron), diagnostic analysers, tissue analysers, laboratory equipment, biological samples, analysis techniques

Physiological measurement devices: e.g. ECG, EEG, spirometry, blood pressure monitors, glucose meters; smart stethoscopes, digital thermometers, biosensors

Genomics and precision medicine: e.g. DNA sequencing, CRISPR gene editing, genetic screening; pharmacogenomics, bioinformatics, high-throughput sequencing; microarray technology

Wearable and implantable devices: e.g. fitness trackers, smart watches, continuous glucose monitors; pacemakers, neurostimulators, cochlear implants.

Alternative classifications:

Consumables: e.g. single-use medical products, disposable instruments, sterile packaging

Hardware: e.g. diagnostic devices, imaging systems, surgical tools, prosthetics

Software: e.g. electronic health records, AI-based diagnostics, telehealth platforms

Digital health and software-driven devices: e.g. standalone software, mobile health apps, decision support systems

MedTech design and manufacturing considerations:

Human-centred design: e.g. user-centred design, ergonomics, patient safety, functionality, usability testing, human factors, design processes, innovation

Manufacturing processes: e.g. sterilisation methods, material selection (metals, polymers, ceramics), quality control, regulatory compliance, assembly techniques, fabrication, production standards

Manufacturing techniques: e.g. 3D printing, CNC machining, injection moulding, automation

Quality assurance and risk management: e.g. ISO 13485, ISO 14971, failure mode analysis

Supply chain and distribution: e.g. logistics, procurement (e.g. process, ethics, sustainability), regulatory compliance, packaging.

LO3 **Explore the impact of medical technology on clinical and preventive healthcare settings**

Role of MedTech in healthcare systems:

Clinical environments: e.g. hospitals, ICUs, outpatient clinics, home care

Preventive healthcare: e.g. remote monitoring, wearable tech, predictive analytics

Interventional procedures: e.g. robotic-assisted surgery, AI-powered diagnostics.

Impact of medical technology:

Clinical outcome improvement: e.g. treatment efficacy, recovery times, diagnostic accuracy, patient outcomes, therapy advancements, healthcare improvement, effectiveness

Preventive healthcare devices: e.g. wearable technology, health monitoring, preventive screening, early detection, proactive healthcare, monitoring systems, risk reduction

Patient monitoring systems: e.g. remote monitoring, telehealth, real-time data, continuous observation, health data, patient safety, technology in monitoring

Cost-effectiveness of MedTech: e.g. healthcare economics, return on investment (ROI), cost–benefit analysis, financial impact, affordability, economic evaluation, resource utilisation

Public health impact: e.g. widespread accessibility, health equity, community health, public health improvements, population health, broad impact, societal benefits.

Evidence-based approach and real-world evidence (RWE):

Evidence gathering methods: e.g. clinical trials, post-market surveillance, data analysis, research methodologies, validation studies, empirical evidence, data collection

Clinical trials and regulatory approvals: e.g. randomised controlled trials (RCTs), post-market surveillance (PMS), real-world data (RWD)

Health technology assessment (HTA): e.g. cost-effectiveness studies, economic evaluations, payer reimbursement considerations

Human factors and user experience: e.g. patient-reported outcomes (PROs), clinician usability studies, ergonomic design.

Challenges and considerations:

Interoperability with electronic health records (EHRs), (data standardisation, integration)

Equitable access to MedTech: e.g. affordability, availability, regulatory barriers

Environmental Impact and Sustainability: e.g. eco-friendly materials, recycling, waste management.

LO4 **Review the data management regulations and requirements in the MedTech industry**

Regulatory frameworks and compliance standards:

Medical data protection laws, including GDPR (e.g. data protection principles, consumer rights, legal compliance, user data protection, privacy standards), HIPAA (e.g. health information privacy, security standards, regulatory compliance, patient confidentiality, healthcare privacy); MDR, IVDR

Cybersecurity standards: e.g. ISO 27001, NIST cybersecurity framework, FDA cybersecurity guidance

Risk management and quality assurance: ISO standards including quality management (ISO 13485), risk management (ISO 14971); compliance guidelines, international standards, quality assurance

FDA regulations: e.g. pre-market approval, 510(k) process, regulatory pathways, device authorisation, FDA mandates, compliance procedures.

Data governance and ethical considerations:

Clinical data privacy and confidentiality: e.g. data minimisation, anonymisation

Patient consent and data ownership: e.g. informed consent, patient rights, ethical considerations, privacy protection, confidentiality standards, consent procedures, data-sharing policies, regulatory compliance

AI and machine learning ethics: e.g. bias in algorithms, fairness in decision-making

Medical device reporting requirements: e.g. adverse event reporting, vigilance systems, reporting timelines, regulatory mandates, safety reporting, incident documentation

Information security standards: e.g. encryption, access controls, authentication protocols, data protection, security measures, cybersecurity, patient information security.

Principles of data management and integrity in MedTech:

Electronic health records (EHRs)

Database principles: relational databases (e.g. tables, relations, fields, records, keys, data integrity, referential integrity), non-relational databases (e.g. flat files, data warehouses, data lakes, NoSQL documents); applications and uses

Data storage: e.g. cloud storage, local servers, backup protocols, data retention, storage methods, technology infrastructure, data management

Data integrity and validation: e.g. validation methods, data verification, quality assurance, accuracy checks, data reliability, credibility, integrity standards; audit trails, access controls, backup systems

Interoperability and system integration: HL7 (e.g. message formats, data exchange standards, healthcare connectivity, interoperability guidelines, communication standards); FHIR (e.g. data models, resource definitions, exchange protocols, interoperability frameworks, healthcare data integration)

Data-driven MedTech innovation: e.g. predictive analytics, AI-driven diagnostics.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Review the MedTech sector and the progression opportunities within it</td><td rowspan="2">D1 Evaluate, using a range of real-world examples, the impact of several key advances in science and engineering on the evolution of medical technology and progression opportunities.</td></tr>
<tr><td>P1 Prepare, using a range of real-world examples, a review of the MedTech sector considering the contributions that science and engineering have made to the field of medical technology.

P2 Review, using a range of real-world examples, the opportunities for progression within the MedTech sector.</td><td>M1 Analyse, using a range of real-world examples, the relationship between the MedTech sector and the advancements in science and engineering, and the impact on opportunities for progression.</td></tr>
<tr><td colspan="2">LO2 Explain the key terms, concepts and categories in MedTech design, manufacture and utilisation</td><td rowspan="4">LO2 and LO3

D2 Justify, using an identified medical technology, the impact of an evidence-based approach on the design, manufacture or use of MedTech in a clinical or preventive healthcare setting.</td></tr>
<tr><td>P3 Explain, using a range of real-world examples, the key terms, concepts and categories in the MedTech industry.

P4 Discuss, using a range of real-world examples, the design and manufacturing factors that must be considered when developing medical technology systems.</td><td>M2 Evaluate the key terms, concepts and categories in MedTech design, manufacture and utilisation.</td></tr>
<tr><td colspan="2">LO3 Explore the impact of medical technology on clinical and preventive healthcare settings</td></tr>
<tr><td>P5 Explore, using a range of real-world examples, the impact of medical technology on clinical and preventive healthcare settings.

P6 Discuss, using a range of real-world examples, how an evidence-based approach is used in the application of medical technology to clinical and preventive healthcare settings.</td><td>M3 Evaluate, using a range of real-world examples, the impact of evidence-based medical technology on clinical and preventive healthcare settings.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Review the data management regulations and requirements in the MedTech industry		
P7 Review the relevant legislation and regulatory frameworks governing data management in the MedTech industry. **P8** Discuss the ethics and governance of data management and integrity in the MedTech industry.	**M4** Analyse the data management regulations and requirements in the MedTech industry.	**D3** Evaluate, using an identified medical technology, the effectiveness of the data management regulations and requirements in the MedTech industry.

Recommended Resources

Textbooks

David, Y., Judd, T.M. and Zambuto, R.P. (2020) 'Introduction to medical technology management practices', in *Clinical Engineering Handbook* (pp.166-177). 2nd Ed. London: Academic Press.

Geisler, E. and Heller, O. (2012) *Management of Medical Technology: Theory, Practice and Cases*. Berlin: Springer Science & Business Media.

Kramme, R., Hoffmann, K.P. and Pozos, R.S. eds. (2011) *Springer Handbook of Medical Technology.* Berlin: Springer Science & Business Media.

Woods, M.B. and Woods, M. (2011) *Ancient Medical Technology: From Herbs to Scalpels*. Minneapolis: Twenty-First Century Books.

Websites

www://evolutionoftheprogress.com/history-of-medtech/	The Evolution of Progress: The History of Medtech (Blog)
www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy	Medical technology strategy (Policy Paper)
www.greenlight.guru/blog/guide-clinical-data-management-medtech	Ultimate Guide to Clinical Data Management in MedTech (Blog)
www.medtecheurope.org/	MedTech Europe (Resource)
www.medtecheurope.org/new-medical-technology-regulations/	Medical Technology Regulations (Resource)
pmc.ncbi.nlm.nih.gov/articles/PMC8260574/	Medical Technologies Past and Present: How History Helps to Understand the Digital Era (Article)
www.supplychain.nhs.uk/categories/medical-technology/	Medical Technology (Resource)

Links

This unit links to the following related units:

Unit 403: Risk Management (ISO 14971)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 505: Manufacturing Processes

Unit 509: ISO Standard Auditing for Medical Devices

Unit 510: Good Practices in MedTech

Unit 515: Advanced Manufacturing.

Unit 402: Quality Management Systems (ISO 13485)

Unit code: J/651/7100

Unit level: 4

Credit value: 15

Introduction

Ensuring quality and safety in the design and production of medical devices is of vital importance in the modern healthcare industry. ISO 13485, a globally recognised standard for quality management systems in the medical technology sector, provides a comprehensive framework that addresses these critical concerns. This unit will introduce students to the principles and applications of ISO 13485, equipping them with the knowledge and skills required to navigate this standard effectively within the MedTech industry.

The primary aim of this unit is to provide students with an understanding of the ISO 13485 standard and its significance in the MedTech sector. By examining the rationale behind the introduction of ISO standards and the essential features of ISO 13485, students will gain a thorough understanding of this critical quality management system.

The unit explores a wide range of topics essential to understanding and implementing ISO 13485. Key areas of focus include the standardisation rationale, the development of quality management standards, and the various quality management techniques that support ISO 13485. Students will study the specific features of ISO 13485, including its requirements for design controls, manufacturing controls and regulatory approvals. The unit will cover the benefits and challenges of implementing ISO 13485, providing students with a balanced view of its impact on organisational operations. Students will have the opportunity of exploring how the eight clauses of the ISO 13485 standard can be applied to a MedTech scenario.

On successful completion of this unit, students will have developed a set of skills in quality management and ISO 13485 compliance specific to the MedTech sector. These skills are directly linked to a variety of employment opportunities within the MedTech industry, including in roles such as Quality Assurance Manager, Regulatory Affairs Specialist and Compliance Officer.

Learning Outcomes

By the end of this unit, a student will be able to:

LO1 Review the rationale for introducing ISO standards into the MedTech sector

LO2 Discuss the essential features of the ISO 13485 standard used in the MedTech sector

LO3 Explore the benefits and challenges to an organisation implementing the ISO 13485 standard within the MedTech sector

LO4 Explain how the ISO 13485 standard can be applied to a given MedTech scenario.

Essential Content

LO1 **Review the rationale for introducing ISO standards into the MedTech sector**

Standardisation rationale:

Patient safety: e.g. product consistency, compliance framework, harmonisation, international alignment, safety protocols, risk mitigation strategies, validation parameters, conformity assessment

Industry benchmarks: e.g. quality metrics, performance standards, safety thresholds, compliance indicators

Regulatory requirements: e.g. legislative framework, statutory obligations, governance structure.

Development of standards:

ISO 9001 development: quality framework, process approach, system integration, documentation hierarchy

Industry standards: sector requirements, cross-industry application; system architecture: quality parameters, control mechanisms.

Quality management techniques:

ISO 9001: e.g. international standard, certification requirements, audit framework; product specifications (e.g. service parameters, quality indicators); compliance metrics (e.g. performance measures, quality objectives)

Total Quality Management (TQM): e.g. process integration, customer satisfaction, employee engagement; continuous improvement cycle (e.g. quality culture, system approach); stakeholder involvement (e.g. process ownership, quality metrics)

Six Sigma: e.g. statistical control, data analysis, process capability; variation reduction (e.g. defect prevention, measurement systems); control charts (e.g. process metrics, performance indicators)

Lean: e.g. waste identification, value stream, process efficiency; resource optimisation (e.g. workflow analysis, capacity utilisation; value creation, process standardisation, efficiency metrics).

Evolution from ISO 9001:

ISO 13485 timeline: standard evolution, regulatory adaptation, industry requirements

Version updates: compliance changes, requirement modifications

Implementation guidance: e.g. transition periods, standard interpretation

ISO 13485 updates: introduction (1996), revisions (2003, 2016), regulatory adaptation

Company impact: enterprise-wide influence, management oversight, component sourcing.

Electronic QMS concepts:

Digital compliance management, software tools for product realisation, market surveillance.

LO2 **Discuss the essential features of the ISO 13485 standard used in the MedTech sector**

ISO 13485 definition:

QMS standard for design, production, installation, servicing and manufacturing of medical devices

Standard scope: application parameters, requirement specifications

Design controls: production requirements, service provisions

Installation qualifications: performance qualification, process validation

Manufacturing controls: quality parameters, system requirements.

Regulatory approvals:

CE Mark, UKCA, FDA compliance integration.

ISO 9001 versus ISO 13485:

Similarities: formal QMS (e.g. risk assessment, continuous improvement such as Deming Cycle, infrastructure, staff competency), end-user focus (e.g. user experience, dynamic data collection)

Differences: e.g. risk management, post-market surveillance, enhanced documentation.

ISO 13485 key requirements:

Device master record: e.g. product specifications, design history, development documentation; process parameters (e.g. control measures, quality criteria); test specifications (e.g. acceptance criteria, validation protocols); feedback system for non-conformance

Quality control systems: e.g. measurement systems (e.g. monitoring protocols, control parameters), quality metrics (e.g. performance indicators, acceptance criteria), release procedures (e.g. inspection protocols, test methodologies)

Essential documentation, including quality manual; policy documentation (e.g. procedure hierarchy, work instruction); form templates (e.g. record formats, document control); system architecture (e.g. process maps, interaction matrices)

Standard operating procedures (SOPs): e.g. procedure documentation (e.g. work instructions, reference materials), training materials (e.g. competency requirements, qualification criteria), document control (e.g. revision history, change management)

MDR compliance: e.g. supply chain accountability, vendor selection, quality assurance at each step; approval requirements (e.g. certification marks such as conformity assessment, regulatory submissions), international standards (e.g. regional requirements, local regulations), compliance evidence (e.g. technical documentation, submission dossiers).

LO3 **Explore the benefits and challenges to an organisation implementing the ISO 13485 standard within the MedTech sector**

Benefits:

Compliance facilitation: e.g. simplifying adherence to regulations, compliance assurance, system effectiveness, performance optimisation

Market access: e.g. gaining entry to regulated markets, competitive advantage, customer confidence

Product consistency: e.g. reliability, quality

Cost reduction: e.g. identifying and eliminating inefficiencies

Risk reduction: e.g. efficiency gains, quality improvements

Benchmark for quality management: e.g. international certification standard, global recognition for quality, regulatory alignment.

Challenges:

Certification costs: e.g. audit expenses, consultancy fees, internal training, maintenance standards, audit trails, system maintenance, upgrade requirements, resource allocation, documentation costs, system support, infrastructure requirements

Risk of non-adherence: e.g. system breakdowns, potential operational failures; regulatory penalties (e.g. fines and sanctions; patient safety hazards)

Organisational impact: e.g. resource requirements (e.g. management structure, responsibility matrix); training needs (e.g. competency assessment, skill requirements), system integration (e.g. process alignment, departmental coordination)

Software considerations: e.g. system requirements (e.g. integration parameters, compatibility issues), data management (e.g. security protocols, access controls), validation requirements (e.g. system verification, performance criteria)

Company-wide relevance: e.g. compliance (e.g. technical development, clinical research, customer service, commercial viability).

ISO 13485 investment considerations:

Small business challenges: e.g. resource limitations, scalability and expertise

Software as a Medical Device (SaMD): unique compliance requirements and evolving regulations

Mandatory requirement in some regions: essential for market entry in certain areas

Risk-based assessment framework: comprehensive approach to risk management.

LO4 **Explain how the ISO 13485 standard can be applied to a given MedTech scenario**

The eight clauses of ISO 13485:

Scope: application boundaries (e.g. inclusion criteria, exclusion parameters), device categories (e.g. classification criteria, regulatory scope)

Normative references: standard references (e.g. regulatory guidelines, compliance requirements), supporting documentation (e.g. reference materials, guidance documents)

Terms and definitions: e.g. technical vocabulary (e.g. industry terminology, regulatory definitions), standard interpretations (e.g. classification criteria, terminology framework)

QMS requirements: e.g. system structure (e.g. documentation hierarchy, control mechanisms), record requirements (e.g. system parameters, process controls)

Management responsibility: e.g. leadership requirements (e.g. policy framework, review criteria), responsibility matrix (e.g. authority levels, accountability structure)

Resource management: e.g. competency requirements (e.g. equipment specifications, infrastructure needs), training framework (e.g. qualification criteria, resource allocation)

Product realisation: design inputs (e.g. production parameters, validation criteria), process controls (e.g. verification requirements, acceptance standards)

Measurement and improvement: performance metrics (e.g. analysis methods, improvement indicators), monitoring systems (e.g. measurement criteria, evaluation parameters).

Audit preparation:

Internal assessment: e.g. documentation review, process evaluation, gap analysis; compliance checking (e.g. system verification, readiness assessment)

External audit: e.g. certification requirements (e.g. evidence compilation, audit trails), compliance documentation (e.g. system demonstration, performance evidence).

Continuous improvement:

Monitoring systems: e.g. performance indicators, quality metrics, trend analysis; system effectiveness (e.g. process efficiency, outcome measures)

Corrective actions: e.g. non-conformance categories, root cause analysis, correction methods; prevention strategies (e.g. system updates, improvement plans).

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Review the rationale for introducing ISO standards into the MedTech sector</td><td rowspan="2"></td></tr>
<tr><td>P1 Review, using a range of real-world examples, the rationale for introducing ISO standards into the MedTech sector.

P2 Discuss, using a range of real-world examples, the evolution of quality management standards within the MedTech sector.</td><td>M1 Analyse, using a range of real-world examples, the rationale and evolution of ISO standards in the MedTech sector.</td><td>D1 Critically evaluate, using a range of real-world examples, the evolution of the ISO 13485 standard within the MedTech sector.</td></tr>
<tr><td colspan="2">LO2 Discuss the essential features of the ISO 13485 standard used in the MedTech sector</td><td rowspan="4">LO2 and LO3

D2 Justify, using a range of real-world examples, the implementation of the ISO 13485 standard within the MedTech sector, considering the benefits and challenges.</td></tr>
<tr><td>P3 Explain, using a range of real-world examples, the similarities between the ISO 9001 and ISO 13485 standards for quality management.

P4 Discuss, using a range of real-world examples, the essential features of the ISO 13485 standard used in the MedTech sector.</td><td>M2 Assess, using a range of real-world examples, the essential features of the ISO 13485 standard used in the MedTech sector.</td></tr>
<tr><td colspan="2">LO3 Explore the benefits and challenges to an organisation implementing the ISO 13485 standard within the MedTech sector</td></tr>
<tr><td>P5 Explore, using a range of real-world examples, the benefits for an organisation implementing the ISO 13485 standard within the MedTech sector.

P6 Explore, using a range of real-world examples, the challenges for an organisation implementing the ISO 13485 standard within the MedTech sector.</td><td>M3 Evaluate, using a range of real-world examples, the benefits and challenges for an organisation implementing the ISO 13485 standard within the MedTech sector.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Explain how the ISO 13485 standard can be applied to a given MedTech scenario		
P7 Explain how the eight clauses of the ISO 13485 standard are applied to a given MedTech scenario. **P8** Discuss the audit preparation and continuous improvement requirements of the ISO 13485 standard as applied to a given MedTech scenario.	**M4** Analyse the effectiveness of the application of the ISO 13485 standard as applied to a given MedTech scenario.	**D3** Evaluate the effectiveness of the application of the ISO 13485 standard to the given MedTech scenario.

Recommended Resources

Textbooks

Abuhav, I. (2017) *ISO 9001: 2015: A Complete Guide to Quality Management Systems*. Boca Raton: CRC Press.

Abuhav, I. (2018) *ISO 13485: 2016: A Complete Guide to Quality Management in the Medical Device Industry*. 2nd Ed. Boca Raton: CRC Press.

Juuso, I. (2022) *Developing an ISO 13485-Certified Quality Management System: An Implementation Guide for the Medical-Device Industry*. Boca Raton: CRC Press.

Myhrberg, E.V., Raciti, J. and Myhrberg, B.L. (2019) *A Practical Field Guide for ISO 13485: 2016: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*. Milwaukee: Quality Press.

Natarajan, D. (2017) *ISO 9001 Quality Management Systems*. Cham: Springer International Publishing.

Teixeira, M.B. (2019) *Design Controls for the Medical Device Industry*. 3rd Ed. Boca Raton: CRC Press.

Websites

www.greenlight.guru/blog/iso-13485-qms-medical-device	ISO 13485: Ultimate Guide to Medical Devices QMS (Article)
www.iso.org/standard/59752.html	ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (Resource)
www.iso.org/standard/62085.html	ISO 9001:2015 (Resource)
www.itgovernance.co.uk/blog/how-to-implement-iso-9001-step-by-step-guide	How to Implement ISO 9001: Step-by-Step Guide (Article)
medium.com/@akitrablog/a-short-guide-to-iso-13485-compliance-1440992c7574	A Short Guide To ISO 13485 Compliance (Blog)
www.qualio.com/blog/iso-13485-standard	ISO 13485: the essential guide (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 403: Risk Management (ISO 14971)

Unit 406: Regulatory Compliance

Unit 502: Computer Systems Validation

Unit 509: ISO Standard Auditing for Medical Devices

Unit 510: Good Practices in MedTech

Unit 513: Quality by Design.

Unit 403: Risk Management (ISO 14971)

Unit code: **K/651/7101**

Unit level: **4**

Credit value: **15**

Introduction

The MedTech sector plays a pivotal role in ensuring patient safety and regulatory compliance through effective risk management practices. In this context, the ISO 14971 standard is paramount for professionals engaged in the medical device industry. This unit aims to give students an understanding of risk management principles specifically tailored for MedTech, covering the evolution, essential features, benefits, challenges and real-world applications of ISO 14971.

The primary goal of this unit is to introduce students to the complexities of risk management within the MedTech sector. By examining the principles, scope and evolution of risk management, students will gain a foundation in understanding the regulatory landscape and its historical context. Exploring ISO 14971, students will learn to identify, evaluate and manage the risks associated with medical devices, ensuring safety and compliance across the product life cycle. This unit is essential for those aspiring to succeed in the MedTech industry, providing the necessary skills to navigate the complex regulatory environments and manage risks effectively.

The unit explores a wide range of topics essential to understanding and implementing ISO 14971. Key areas of focus include the purpose and evolution of risk management within the MedTech sector. Students will study the essential features of ISO 14971, including its requirements for risk assessment, control and management planning. The unit will cover the benefits and challenges of implementing ISO 14971, providing students with a balanced view of its impact on organisational operations. Students will have the opportunity of exploring how the ISO 14971 standard can be used to develop a basic risk management plan for a MedTech scenario.

On successful completion of this unit, students will have acquired critical skills in assessment, evaluation, management and documentation of risk within the MedTech sector. They will be able to develop basic risk management plans, conduct hazard analysis and utilise tools such as FMEA and FTA. These competencies are directly linked to roles such as Project Manager, Quality Assurance team member, Regulatory Affairs Specialist and Safety Officer.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Review the principles, scope and evolution of risk management in MedTech

LO2 Discuss the essential features of the ISO 14971 standard in the MedTech sector

LO3 Explore the benefits and challenges for an organisation implementing the ISO 14971 standard within the MedTech sector

LO4 Explain how the ISO 14971 standard can be applied to a given MedTech scenario.

Essential Content

LO1 Review the principles, scope and evolution of risk management in MedTech

Risk concepts:

Key definitions: risk, hazard, intended use, foreseeable misuse, residual risk, safety

Probability: frequent, probable, occasional, remote, improbable, other device-specific terms

Severity of harm: minor, major, critical, fatal, other device-specific terms

Possible outcomes: e.g. probability analysis, severity of harm combinations; insignificant or negligible risk, investigate further risk reduction, unacceptable risk

Risk management principles: e.g. identification, analysis, evaluation, control, communication, documentation

Risk mitigation and prevention: incorporating risk assessment in QMS

Intended use and foreseeable misuse: regulatory considerations, user behaviour.

Historical context:

Evolution of risk management: e.g. development timeline, regulatory changes, industry needs, standard updates, evolution of risk management practices, sector-specific adaptations

Influences: e.g. statistical models, industrial revolution, Six Sigma, Lean, TQM

Non-MedTech sectors: e.g. automotive, aerospace, nuclear industries informing MedTech risk protocols

Risk discovery: stages of manufacturing process, including initiation phase (e.g. project vision, funding, objectives), planning phase (e.g. project plan, scope, budget, timeline), development phase (e.g. prototype development, product build, iterative development), testing and validation phase (e.g. functional, usability, compliance testing), deployment and post-market phase (e.g. manufacturing, distribution, logistics, customer liaison)

Roles at each stage (e.g. Project Sponsor, Designer, Software and Hardware Engineer, QA testing team, production team, surveillance team, sales and marketing team); Risk Manager at each stage; risk discovery at each stage.

Standard evolution:

Iterative updates: 1996, 2003, 2012, 2020

Gradual rollouts: three-year transition periods

Regulatory alignment: MDR, IVDR, AIMDD, EN 1441, ISO 13485.

Principles and scope:

Focus of ISO 14971: risks in medical devices, IVD, SaMD

Scope: risk identification, mitigation, prevention

Regulatory integration: ISO 13485, EU MDR, IVDR, FDA requirements

Compliance frameworks: AIMDD, EN 1441.

LO2 **Discuss the essential features of the ISO 14971 standard in the MedTech sector**

ISO 14971 key terms:

Benefit: definition (e.g. positive outcome, intended device use, individual health, other care system); examples (e.g. quality of life, improved diagnosis speed/accuracy, better clinical outcomes, improved patient throughput)

Harm: negative impact, targets, e.g. people, systems, public health

Hazard: definition, examples, e.g. electromagnetic, thermal, mechanical, biological, chemical

Hazardous situation: definition, examples e.g. lifting device, plugging in device, standing without shielding

Intended use: definition (e.g. product, process, service); use according to (e.g. specifications, instructions and information provided by the manufacturer); off-label use

Reasonably foreseeable misuse: definition (e.g. outside intended use, within anticipated boundaries); types (e.g. intentional, unintentional); designs to minimise risk of misuse

User testing: identify foreseeable misuse, allow design changes, improve user instructions

Residual risk: definition, examples

Risk combination: probability and severity of harm

Risk control: making decision, reduce risk, maintain risk levels

Safety: freedom from unacceptable risk.

Risk management plan:

Plan concepts: structured approach, stakeholder responsibilities, compliance tracking plan contents; product definition, scope of activities, intended use, risk management

Activities, roles and responsibilities: e.g. risk management identification team, risk acceptability criteria, methods to verify risk control, capture of post-production information, Medical Device Safety Officer (MDSO), Medication Safety Officer (MSO).

Risk assessment:

Hazard identification: e.g. biological, chemical, mechanical, electrical, cybersecurity risks

Risk quantification: e.g. probability–severity analysis, risk charts, risk matrices, ranking systems

Failure mode and effects analysis (FMEA): systematic failure tracking, severity prioritisation

Fault tree analysis (FTA): identifying failure pathways, impact estimation.

Risk control and mitigation:

Inherent safety by design, e.g. engineering solutions, fail-safe mechanisms

Protective measures, e.g. safety alarms, interlock systems, user interface safeguards

Information for safety, e.g. user manuals, labelling, training programmes.

Residual risk evaluation:

Acceptability criteria, regulatory compliance.

Risk review:

Periodic assessment, risk–benefit trade-offs, summary of activities, overall risk acceptability.

Production and post-production activities:

Collect and review relevant information: e.g. statistical monitoring, integration with monitoring and feedback processes, MHRA Yellow Card Scheme

Collect relevant device information: e.g. supply chain, alternative devices, alternative therapies, active collection

Information review: relevance, hazard identification, estimate of risk

Required actions: review risk file, determine new risk assessments, implement additional control.

LO3 **Explore the benefits and challenges for an organisation implementing the ISO 14971 standard within the MedTech sector**

Benefits:

Compliance assurance: e.g. regulatory alignment, certification achievement, audit readiness

Global market entry: e.g. international recognition, competitive advantage, barrier reduction, approval ease, stakeholder confidence (e.g. credibility boost, stakeholder satisfaction)

Risk management: e.g. proactive identification, improved patient safety, consistent practices; comprehensive assessment, detailed analysis, risk prioritisation, mitigation planning

Continuous improvement: e.g. regular updates, iterative enhancements, feedback integration

Risk control measures: e.g. preventive actions, corrective mechanisms, control implementation

Post-market surveillance: e.g. continuous monitoring, data collection, trend analysis

Documentation rigour: e.g. comprehensive records, traceability maintenance, audit readiness.

Challenges:

Cost implications: e.g. financial investment, budgetary impact, cost–benefit analysis; resource allocation (e.g. budget considerations, personnel assignment, resource dedication); cross-functional training (e.g. team education, skill development, multi-disciplinary involvement)

Implementation complexity: e.g. multi-faceted approach, detailed planning, thorough understanding; documentation requirements (e.g. extensive records, detailed logs, resource intensive); time-intensive processes (e.g. detailed analysis, lengthy procedures, extended timelines)

Cultural adaptation: e.g. organisational change, employee engagement, mindset shift; interdepartmental coordination (e.g. collaboration necessity, communication channels, teamwork); knowledge transfer (e.g. expertise sharing, continuity planning, training programmes)

Dynamic risk landscape: e.g. evolving threats, changing circumstances, adaptive strategies

Real-world data incorporation: e.g. data collection, integration challenges, update mechanisms

Additional costs: e.g. training and consultancy costs, hardware and software requirements, upgrade requirements, reallocation of resources, infrastructure.

Implementation considerations:

Resource planning, system integration, process validation, staff training, timeline creation, resource allocation

Challenges for small markets and low-risk devices: e.g. low-risk device considerations, markets without compulsory ISO 13485 QMS, business risk management

ISO 14971 interaction with ISO 13485 and MDR/IVDR

Alignment importance, requirement integration, system coupling

Trend analysis and surveillance: e.g. periodic safety updates, real-world performance evaluation

Medical device reporting (MDR), field safety corrective actions (FSCA): e.g. alerts (e.g. national patient safety alerts), recall management, regulatory notifications

Risk communication: e.g. transparent reporting, stakeholder engagement, patient information strategies.

Risk categories:

Design and development risks: e.g. material safety, human factors engineering, prototype testing

Manufacturing and production risks: e.g. process validation, contamination control, supply chain risks

Pre-market risk evaluation: e.g. clinical validation, usability testing, software security testing

Post-market risk monitoring: e.g. incident reporting and corrective actions (CAPA) (e.g. compliance obligations, adverse event tracking, MHRA Yellow Card Scheme).

LO4 **Explain how the ISO 14971 standard can be applied to a given MedTech scenario**

Risk management plan (RMP) development:

Identify stakeholders and roles: e.g. Project Manager (e.g. Risk Coordinator, Risk Management Leader, Project Risk Planner, Risk Management Head, Project Risk Officer); quality assurance team (e.g. risk quality control, QA Specialist, Quality Risk Reviewer, QA oversight, quality inspection team); Regulatory Affairs Specialist (e.g. Regulatory Compliance Officer, Compliance Specialist, Regulatory Advisor, Regulatory Risk Expert, Compliance Coordinator); design and development team (e.g. Engineer, Designer, R&D Specialist, Product

Safety Developer, Design Risk Analyst); Clinical Expert (e.g. Medical Risk Evaluator, Clinical Safety Officer, Healthcare Risk Assessor, Clinical Risk Specialist, Medical Advisor); Safety Officer (e.g. Safety Manager, Risk Safety Officer, Health and Safety Specialist, Safety Risk Expert, Safety Compliance Officer)

Risk assessment methodologies, including preliminary hazard analysis (PHA), failure modes and effects analysis (FMEA) and fault tree analysis (FTA)

Risk acceptance criteria: risk matrix (severity versus probability model).

Risk identification

Identification: e.g. hazard types, risk catalogue, risk discovery, risk element identification, preliminary hazard analysis

Analysis: e.g. hazard severity, hazard probability, hazard identification techniques, hazard characterisation, hazard severity index

Device-related hazards: e.g. battery overheating, electrode detachment, inaccurate readings

Software hazards: e.g. data corruption, signal interference, algorithm bias

Cybersecurity hazards: e.g. unauthorised access, data breaches, hacking attempts

Use-related hazards: e.g. misinterpretation of readings, incorrect device placement

Environmental hazards: e.g. electromagnetic interference, extreme temperatures affecting sensors.

Risk evaluation:

Risk criteria, acceptable risk, risk acceptance, risk decision-making, risk tolerance.

ISO 14971 risk estimation matrix: risk scoring, probability–impact grid, risk quantification, risk evaluation matrix, risk rating scale.

Risk control measures:

Risk treatment, risk minimisation, mitigation strategies, risk mitigation plan, risk response.

Risk–benefit analysis:

Residual risk: e.g. post-mitigation risk, residual risk identification, residual risk acceptance, residual risk analysis, risk–benefit ratio

Benefit–risk analysis: e.g. benefit assessment, risk–benefit comparison, benefit–risk balance, therapeutic benefit evaluation, risk–reward analysis.

Implementation strategies:

Integration with design process: e.g. design phase risk management, integrated risk planning, embedded safety, design safety integration, collaborative risk design

Cross-functional collaboration: team collaboration, multi-disciplinary approach, cross-departmental risk, collaborative risk review, integrated teams

Life cycle approach: e.g. life cycle risk management, ongoing risk assessment, end-to-end risk strategy, full cycle risk, continuous life cycle monitoring

Iterative risk review: e.g. periodic risk analysis, regular reviews, iterative process, continuous improvement review, ongoing risk revaluation

Continual improvement process: e.g. improvement strategies, process optimisation, continual enhancement, progressive risk management, ongoing refinement.

Risk management review and documentation:

Risk management file: e.g. update risk documentation, risk record, comprehensive record, risk archive, record-keeping system

Risk management plan: e.g. project risk plan, risk planning document, risk strategy plan, risk management strategy, risk action plan

Risk management report: e.g. risk summary, risk findings report, final risk report, risk outcome report, risk review report

Hazard log: e.g. risk register, risk log, hazard recording, hazard tracker, safety concerns log

Traceability matrix: e.g. risk traceability, requirements traceability, risk mapping, traceability documentation, traceability analysis

Incident reports: e.g. event reporting, safety incident report, adverse event documentation, incident tracking, reportable incidents.

Post-market surveillance and risk monitoring:

Post-market surveillance (PMS) plan: e.g. track real-world performance, user feedback, incident reports, new hazard identification

Corrective and preventive actions (CAPA) for unexpected risks

Periodic safety update reports (PSUR) for regulatory compliance.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Review the principles, scope and evolution of risk management in MedTech</td><td rowspan="2"></td></tr>
<tr><td>P1 Review, using a range of real-world examples, the key concepts and historical context of risk management in the MedTech sector.

P2 Discuss, using a range of real-world examples, how risk management has evolved into its current scope and purpose within the MedTech sector.</td><td>M1 Analyse, using a range of real-world examples, the concepts and evolution of risk management standards in the MedTech sector.</td></tr>
<tr><td colspan="2">LO2 Discuss the essential features of the ISO 14971 standard in the MedTech sector</td><td rowspan="5">LO2 and LO3

D2 Justify, using a range of real-world examples, the implementation of the ISO 14971 standard within the MedTech sector, considering the benefits and challenges.</td></tr>
<tr><td>P3 Explain, using a range of real-world examples, the key terms of the ISO 14971 standard used in the MedTech sector.

P4 Discuss, using a range of real-world examples, the essential features of the ISO 14971 standard used in the MedTech sector in pre-production, production and post-production activities.</td><td>M2 Assess, using a range of real-world examples, the essential features of the ISO 14971 standard used in a range of production activities within the MedTech sector.</td></tr>
<tr><td colspan="2">LO3 Explore the benefits and challenges for an organisation implementing the ISO 14971 standard within the MedTech sector</td></tr>
<tr><td>P5 Explore, using a range of real-world examples, the benefits for an organisation implementing the ISO 14971 standard within the MedTech sector.

P6 Explore, using a range of real-world examples, the challenges for an organisation implementing the ISO 14971 standard within the MedTech sector.</td><td>M3 Evaluate, using a range of real-world examples, the benefits and challenges for an organisation implementing the ISO 14971 standard within the MedTech sector.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Explain how the ISO 14971 standard can be applied to a given MedTech scenario		
P7 Explain how the ISO 14971 standard can be applied to develop a basic risk management plan for a given scenario within the MedTech sector. **P8** Explain how the ISO 14971 standard can be applied to develop a range of implementation strategies, risk documentation and post-market surveillance activities for a given scenario within the MedTech sector.	**M4** Analyse the effectiveness of the application of the ISO 14971 standard to a given scenario within the MedTech sector.	**D3** Evaluate the effectiveness of the application of the ISO 14971 standard to a given MedTech scenario.

Recommended Resources

Textbooks

Cosgriff, P.S. and Memmott, M.J. (2024) *Writing In-House Medical Device Software in Compliance with EU, UK, and US Regulations*. Boca Raton: CRC Press.

Douville, S. ed. (2023) *Advanced Health Technology: Managing Risk While Tackling Barriers to Rapid Acceleration.* Boca Raton: CRC Press.

Elahi, B. (2021) *Safety Risk Management for Medical Devices.* 2nd Ed. London: Academic Press.

Haimes, Y. Y. ed. and Sage, A.P. series ed. (2015) *Risk Modeling, Assessment, and Management.* New York: John Wiley & Sons.

Juuso, I. and Pöyhönen, I. (2023) *Medical-Grade Software Development: How to Build Medical-Device Products That Meet the Requirements of IEC 62304 and ISO 13485*. Boca Raton: CRC Press.

Wreh, E. (2023) *Medical Device Regulation: FDA-CDRH Manufacturing, Policies and Regulation Handbook*. London: Academic Press.

Websites

www.bsigroup.com/globalassets/meddev/localfiles/fr-fr/whitepapers/risk_management_web.pdf	Risk management for medical devices and the new ISO 14971 (White Paper)
www.gov.uk/drug-device-alerts	Gov.UK Alerts, recalls and safety information: medicines and medical devices (Resource)
www.greenlight.guru/blog/iso-14971-medical-device-risk-management	Understanding ISO 14971 Medical Device Risk Management (Blog)
www.greenlight.guru/blog/iso-14971-risk-management	ISO 14971 Risk Management for Medical Devices: The Definitive Guide (Blog)
www.iso.org/standard/72704.html	ISO 14971: 2019 Medical devices – Application of risk management to medical devices (General reference)

medicaldevicehq.com/articles/the-illustrated-guide-to-risk-management-for-medical-devices-and-iso-14971/	The illustrated guide to risk management for medical devices and ISO 14971 (Blog)
www.qservegroup.com/eu/en/i1253/risk-management--mdr-vs-iso-14971-2019-requirements	Risk Management: MDR vs ISO 14971: 2019 requirements (Blog)
www.qualio.com/blog/iso-14971	A comprehensive guide to ISO 14971: Risk management for medical devices (Blog)
yellowcard.mhra.gov.uk/	MHRA Welcome to the Yellow Card reporting site (Resource)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 406: Regulatory Compliance

Unit 503: Managing a MedTech Project

Unit 509: ISO Standard Auditing for Medical Devices

Unit 510: Good Practices in MedTech

Unit 513: Quality by Design.

Unit 404: Applied Programming

Unit code: **L/651/7102**

Unit level: **4**

Credit value: **15**

Introduction

In this technologically advancing world, programming forms the backbone of various industries, including the healthcare sector, where accuracy, reliability, performance and innovation are of vital importance. This unit is designed to equip students with an understanding and practical experience in the various fields of programming that are required in medical applications. This unit is essential for those aiming to pursue a career in the field of MedTech and healthcare software development.

The primary aim of this unit is to provide students with both theoretical and practical skills in programming, focusing on applications within the medical field. Students will study the fundamental principles of programming, event-driven programming and Object-Orientated Programming (OOP). Students will combine these skills to develop a software solution for the MedTech industry.

The curriculum covers a wide range of topics in programming within the healthcare context. Initial topics introduce basic programming concepts such as variables, data types and control structures, progressing into more complex areas such as data structures, algorithms and error handling. Event-driven programming principles will also be explored, including different raising and handling events, followed by object-orientated programming (OOP) and design patterns. The final part of the unit emphasises the practical application of these elements through the development of a dedicated medical application, incorporating essential concepts such as requirements analysis, program design, testing and deployment.

On successful completion of this unit students will have developed a range of skills. including programming, analytical thinking and software design, preparing them for roles such as Software Developer, Database Administrator, Health Informatics Specialist, MedTech Software Engineer and Systems Analyst.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explore the fundamentals of programming

LO2 Review the principles and components of event-driven programming

LO3 Demonstrate an understanding of Object-Orientated Programming (OOP)

LO4 Develop a programmed solution for an identified medical application.

Essential Content

LO1 **Explore the fundamentals of programming**

Basic programming concepts:

Variables including declaration, assignment, memory management, pointers

Data types including int, char, float, bool, real, string, datetime

Operators, including mathematical (+ / * –, integer division, modulus), logical (AND, OR, NOT, XOR), relational (==, <, >, <>, <=, >=).

Program control structures:

Selection including IF THEN, ELSE, ELSEIF (ELIF), SELECT (SWITCH) CASE

Iteration including FOR, WHILE DO WHILE or REPEAT UNTIL

Subroutines: functions and procedures, parameters and arguments, parameters BY REF and BY VAL, return types, modularity, reusability.

Data structures:

Types: e.g. arrays, lists, stacks, queues, hash tables, dictionaries, enum, struct, linked list

Purposes: e.g. memory management, scalability, performance, benefits and issues.

Algorithms and design theory:

Algorithm design: pseudocode, flowcharts

Recursive programming to include general case, base case, uses, risks, issues, examples

Search algorithms: e.g. linear, binary, conditions of use

Sort algorithms: e.g. bubble sort, quicksort, merge sort, insertion sort

Conditions of use, benefits, limitations.

Error handling and debugging:

Use of an IDE: debugging outputs, setting breakpoints, stepping through and into code, watching variables, inspection windows

Exception handling: Try Catch Except, logging, troubleshooting techniques.

Programming paradigm concepts:

Procedural, object orientated, event driven, functional

Conditions of use, benefits, limitations, suitability for healthcare applications.

Programming languages in MedTech:

Python, C++, Java, R, MATLAB, suitability for healthcare applications.

LO2 **Review the principles and components of event-driven programming**

Core concepts of event-driven programming:

Event loops, event handlers, events, callbacks, delegates/function pointers, asynchronous execution, multi-threading, scheduling.

Advanced event programming concepts:

Concurrency and parallel processing: thread management, race conditions, deadlocks, critical sections

Security in event-driven applications: data encryption, authentication, role-based access control (RBAC)

Testing in event-driven programming: automated UI testing, load testing, integration testing for asynchronous execution.

User Interface Components:

UI tools: windows, forms, buttons, labels, text boxes, list boxes, radio buttons, drop-downs, menu options, dialogs

Layout managers: panels, flow layout, grid layout

UI component operation: raising multiple events, loading and displaying data (file, XML, loading and displaying images, loading and playing audio).

Frameworks and tools:

GUI libraries

IDEs: role, purpose, uses, language-specific (e.g. Visual Studio, Visual Studio Code, IDLE, PyDev, Eclipse, NetBeans, IDEA)

Toolkits: e.g. XAML, WPF, WinUI, Tkinter, JavaFX, IronPython, Jython, PySimpleGUI, Qt, Java SWING, JavaFX.

Medical technology UI considerations:

User interaction: medical software dashboards, touchscreen medical device interfaces

User-centred design: accessibility, medical dashboards, clinical software interface

Healthcare system integration: event-driven architectures in medical devices, monitoring systems, alert systems.

LO3 **Demonstrate an understanding of Object-Orientated Programming (OOP)**

OOP concepts:

Core concepts: classes (including constructors, destructors, class/static variables, properties, behaviour), objects (including instantiation, instance variables, accessor functions), inheritance, polymorphism, encapsulation, abstraction

Object state: initial state, running state, end state, state persistence

Security considerations: e.g. public, private, protected, internal, static use of interfaces, base class considerations

Benefits: e.g. code modularity and reusability, scalability, maintainability.

Data management and storage:

Version control: techniques, e.g. trunk, check-in, check-out, branch, milestones; implementation: e.g. GitHub, AWS Code, PVCS, Azure DevOps Server

Security considerations in OOP: role-based access control, encryption in MedTech applications.

Testing in OOP:

Unit tests, integration tests, behavioural testing, test-driven development (TDD), debugging tools.

OOP design theory:

Design patterns: e.g. factory pattern, abstract factory, singleton, observer pattern, MVC architecture, strategy pattern, dependency injection

SOLID design principles: e.g. single responsibility, open-closed, Liskov substitution, interface segregation, dependency inversion.

Modelling OOP with UML:

Class diagrams including base/parent class, derived/inherited/child class, interfaces, association (e.g. aggregation, composition)

Other UML diagrams, e.g. use case, sequence, activity, state, package, component.

MedTech considerations for OOP:

Role-based access control, encryption in MedTech applications, object mapping to database tables

Medical software development frameworks: e.g. Django, Flask, .NET, Qt, integration of OOP in healthcare applications.

LO4 **Develop a programmed solution for an identified medical application**

Requirements analysis:

Requirements: e.g. user requirements, use cases, functional and non-functional requirements, accessibility

Clinical workflows: patient care processes, data flow, task sequences

Constraints: e.g. knowledge, time, resource, cost; issues and risk register

Stakeholder analysis: e.g. end-users, healthcare professionals, regulatory bodies

Choice of environment: e.g. language, IDE, database, APIs and libraries, version control

Regulatory and compliance requirements: e.g. data privacy, encryption standards, medical regulations (HIPAA, GDPR, FDA, IEC 62304).

Program design:

Software components: e.g. inputs, outputs, data structures, functions and procedures, error handling

Object design: e.g. classes, inheritance, association

User interface design: e.g. wireframe, flowcharts, navigation design

Algorithm designs: e.g. algorithm, selection, flowcharts, pseudocode.

Development of the solution:

Maintainable code: e.g. code descriptors (e.g. code comments, JavaDocs), naming conventions (e.g. Pascal Case, Camel Case, Snake Case), self-documenting code (e.g. appropriate variable names, descriptive function names)

Coding standards: e.g. PEP8

Modularisation: e.g. functions, modules, packages, assemblies; encapsulation (e.g. single return value, minimal use of global variables, minimal use of ByRef).

Testing the solution:

Types of tests: e.g. unit test, integration test, regression test, functional testing, structural testing

Test plan components: e.g. item tested, test data, expected results, actual results, actions

Test data: e.g. normal, boundary, erroneous, extreme

Test actions: e.g. fixing bugs (logical and compile-time), code documentation, updating code base.

Gathering feedback:

Stakeholder feedback: e.g. verbal, survey, questionnaire, meetings, prototype demonstration

Categories: e.g. performance, usability, reliability, efficiency, compliance with regulatory standards

Program optimisation: e.g. using feedback, test results; use of version control.

Deployment:

Platform considerations: e.g. program installation options (e.g. executable, DLL, class files, assemblies); execution environments (e.g. JRE, .NET, PHP, Django, Flask, Apache)

Maintenance: software updates, security patches, documentation maintenance, scalability planning.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explore the fundamentals of programming</td><td rowspan="2">D1 Justify the use of a range of programming techniques and components in the creation of an effective medical application.</td></tr>
<tr><td>P1 Review, using a range of code examples, the fundamental principles and techniques of programming.
P2 Explain, using a range of code examples, the various programming paradigms.</td><td>M1 Assess the effectiveness of the use of programming paradigms and techniques in the context of a medical application.</td></tr>
<tr><td colspan="2">LO2 Review the principles and components of event-driven programming</td><td rowspan="4">LO2 and LO3
D2 Justify the use of event-driven programming and Object-Orientated programming techniques and components in the creation of an effective medical application.</td></tr>
<tr><td>P3 Explain, using a range of programming examples as illustration, the principles of event-driven programming.
P4 Explore, using a range of programming examples as illustration, the different event-driven programming components and libraries that can be used to develop applications for use in the MedTech sector.</td><td>M2 Evaluate, using a range of programming examples as illustration, the effectiveness of a range of event-driven programming principles and components for use in MedTech systems.</td></tr>
<tr><td colspan="2">LO3 Demonstrate an understanding of Object-Orientated Programming (OOP)</td></tr>
<tr><td>P5 Discuss, with examples, a range of Object-Orientated Programming principles in the context of a MedTech application.
P6 Review a range of OOP design principles and modelling techniques that can be applied to a medical application.</td><td>M3 Assess the effectiveness of the application of OOP principles in the context of a MedTech application.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Develop a programmed solution for an identified medical application		
P7 Design, using a range of design tools, a programmed solution that meets client requirements. **P8** Develop, using a range of programming techniques, a programmed solution for an identified medical application based on the identified design. **P9** Gather feedback from a range of relevant stakeholders and types of program testing to inform changes to a developed solution.	**M4** Optimise the programmed solution for an identified medical application using the results of stakeholder feedback and user testing.	**D3** Justify the choices made during the design and development of the programmed solution, showing how they contributed to the effectiveness of the final program.

Recommended Resources

Textbooks

Gamma, E., Helm, R., Johnson, R. and Vlissides, J. (1995) *Design Patterns: Elements of Reusable Object-Oriented Software*. Boston: Addison-Wesley Professional.

Jaworski, M. and Ziadé, T. (2021) *Expert Python Programming: Master Python by Learning the Best Coding Practices and Advanced Programming Concepts*. 4th Ed. Birmingham: Packt Publishing Ltd.

Leach, R.J. (2016) *Introduction to Software Engineering*. 2nd Ed. Boca Raton: CRC Press.

Rangisetti, A.K. (2024) 'Event-Driven Programming', in *Hands-On Object-Oriented Programming: Mastering OOP Features for Real-World Software Systems Development* (pp.467–505). Berkeley CA: Apress.

Wang, W. (2022) *Beginning Programming All-in-one for Dummies*. 2nd Ed. New York: John Wiley & Sons.

Websites

www.geeksforgeeks.org/basics-of-computer-programming-for-beginners/	Basics of Computer Programming For Beginners (General reference)
www.geeksforgeeks.org/introduction-of-object-oriented-programming/	Introduction of Object Oriented Programming (General reference)
www.geeksforgeeks.org/what-is-the-event-driven-programming-paradigm/	What is the Event Driven Programming Paradigm? (Article)
refactoring.guru/design-patterns	Design Patterns (General reference)
www.tutorialspoint.com/computer_programming/computer_programming_basics.htm	Computer Programming – Basics (General reference)
www://quix.io/blog/what-why-how-of-event-driven-programming	The what, why and how of event-driven programming (Blog)
www.w3schools.com/	W3schools (General reference)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 407: Software and UI/UX Design

Unit 501: Data Management and Cybersecurity

Unit 504: Data Analytics

Unit 514: Emerging Trends and Technologies.

Unit 405: Medical Devices

Unit code: **M/651/7103**

Unit level: **4**

Credit value: **15**

Introduction

The landscape of healthcare has been dramatically transformed by the development and integration of medical devices, which include a wide range of technologies from simple diagnostic tools to highly sophisticated therapeutic and monitoring systems.

This unit investigates the complex nature of these instruments, exploring their classifications, life cycle stages, technology readiness levels, and specific case studies. By understanding these aspects, students will gain a comprehensive perspective on how medical devices are developed, regulated and utilised within healthcare systems.

The primary objective of this unit is to give students a thorough understanding of medical devices, covering their wide-ranging classifications, the complete life cycle from design to disposal, and the progression through Technology Readiness Levels (TRLs). Students will learn the critical steps and considerations involved in bringing a medical device to market. The unit also emphasises the critical importance of regulatory frameworks throughout the life cycle, as well as the risks and benefits associated with different types of medical devices.

The unit covers a broad array of topics essential for the field of medical devices. Key areas include the categorisation of devices based on use, functionality and regulatory classes, providing a basic understanding of the range of medical technologies. The stages of the product life cycle are discussed, from initial design and prototyping to manufacturing, quality control and post-market surveillance. The unit examines the different TRLs and their significance in assessing the readiness of medical technologies, from basic research to full-scale deployment. The unit culminates in a detailed investigation into an identified medical device, which brings together all the unit theory and provides students with the knowledge and understanding of real-world challenges in medical device development and management.

Upon successful completion of this unit, students will be able to explain the different classes of medical devices, understand their life cycle processes, explain the TRL stages, and effectively present detailed investigations of specific devices. Such skills are directly applicable to various roles within the medical device industry, including Product Development Specialist, Regulatory Affairs Manager, Quality Assurance professional and Clinical Research Coordinator.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Review the different types of classification used for medical devices

LO2 Explore the stages of the product life cycle for medical devices

LO3 Explain the different technology readiness levels (TRLs) as applied to medical devices

LO4 Present an investigation of an identified medical device to an intended audience.

Essential Content

LO1 **Review the different types of classification used for medical devices**

Classification of MedTech devices:

Single use: e.g. disposable items, infection control, cost considerations, waste management, examples (e.g. syringes, bandages, disposable gloves, catheters, surgical masks)

Multi-use: e.g. reusability, sterilisation methods, maintenance, durability, cost-effectiveness, examples (e.g. endoscopes, surgical instruments, diagnostic equipment, infusion pumps)

Hardware: e.g. components, mechanical parts, electronic devices, integration, diagnostics, interaction with software examples (e.g. ECG machines, X-ray equipment, ultrasound machines, MRI scanners; maintenance, durability, physical wear and tear, hardware updates, hardware–software compatibility)

Software: e.g. medical applications, data management, patient monitoring, compliance, cybersecurity, examples (e.g. EHR systems, telehealth platforms, diagnostic software, decision support systems); software updates (e.g. patches, user interfaces, interoperability with other systems, data security concerns)

Functional categories: e.g. therapeutic devices, diagnostic devices, monitoring devices, assistive devices, surgical instruments, drug delivery systems

Point of use: e.g. home-use devices, clinical-use devices, emergency-use devices, laboratory-use devices.

Classes of MedTech devices

Class I: Low risk, general controls, examples, e.g. bandages, handheld medical tools

Class IIa: Moderate risk, special controls, examples, e.g. infusion pumps, blood pressure monitors

Class IIb: Higher risk, special controls, examples, e.g. ventilators, orthopaedic implants

Class III: Highest risk, pre-market approval, examples, e.g. pacemakers, stents.

Risks and benefits:

Risks: e.g. safety concerns, device malfunctions, user error, infection risk from reuse, allergic reactions, regulatory hurdles, electrical hazards, software vulnerabilities, data breaches

Benefits: e.g. improved patient outcomes, enhanced diagnostic accuracy, treatment efficiency, user convenience, cost savings, reduced hospital stays, increased access to care, better patient monitoring

Regulation framework overview: regulatory bodies (e.g. FDA (USA), MHRA (UK), EMA (EU), WHO global standards), compliance requirements, approval processes, documentation, minor aspects

Key regulations: e.g. Medical Device Regulation (MDR), In Vitro Diagnostic Regulation (IVDR), ISO 13485 (Quality Management System for Medical Devices), Engineering Health Technical Memoranda (HTM) for Medical Gas Pipeline Systems (MGPS).

LO2 **Explore the stages of the product life cycle for medical devices**

Design and prototyping concepts:

Concept development: e.g. idea generation, identifying clinical needs, market research, proof of concept, user feedback integration, feasibility studies, research, development

Initial design: e.g. CAD modelling, material selection, functional and safety testing, rapid prototyping techniques, design validation, engineering specifications, user feedback

Prototyping: e.g. iterative development, functionality testing, refinement, user trials

Design validation: compliance checks, safety testing, clinical evaluation, iteration.

Manufacturing and development concepts:

Manufacturing: e.g. design for manufacturing (DFM), production process optimisation, quality control measures, regulatory compliance, scaling production, procurement, logistics, supplier management, cost control

Supply chain management: e.g. material sourcing, inventory control, logistics, vendor partnerships

Preclinical testing: e.g. laboratory testing, biocompatibility testing, performance assessment, mechanical validation

Clinical trials and validation: e.g. feasibility studies, randomised controlled trials (RCTs), regulatory submission, post-market surveillance planning.

Fundamentals of quality control:

Inspection: e.g. component testing, device testing, functional verification, adherence to standards

Packaging: e.g. sterilisation, robust packaging, labelling, instructions, regulatory compliance

Sterilisation: e.g. methods, autoclaving, gamma irradiation, ethylene oxide, UV-C

Distribution: e.g. warehousing, transportation, distribution channels, global logistics

Regulatory approval and market entry: e.g. risk assessment, submission of technical documentation, notified body audits, CE marking, FDA approval.

Post-market surveillance concepts:

Adverse event reporting, product recalls, user feedback, iterative improvement, life cycle extension, continuous improvement, software updates, device recall management.

End of Life concepts:

Disposal: e.g. proper disposal methods, environmental concerns, hazardous material protocols

Recycling: e.g. sustainable practices, materials reclamation, circular economy, compliance.

LO3 **Explain the different technology readiness levels (TRLs) as applied to medical devices**

TRL Overview and definition:

Technology readiness levels (TRLs), standardised framework, medical device, innovation process, risk assessment, feasibility evaluation, scalability considerations, preclinical versus clinical readiness, FDA versus EU MDR TRL interpretation.

The nine TRLs:

TRL 1: Basic principles observed and reported, initial observations, theoretical research, literature studies

TRL 2: Technology concept, application formulation, analytical models, practical ideas

TRL 3: Experimental proof-of-concept, laboratory testing, feasibility assessments, early-stage trials

TRL 4: Technology validation, lab environment, animal models, prototype development, preliminary functionality, sub-system validation, bench testing, material and durability studies

TRL 5: Relevant environment trials, system/subsystem demonstrations, integration testing, preclinical studies, prototype refinement, usability testing

TRL 6: Full system prototype demonstration, relevant operational environments, pre-commercial preparations, real-world scenario simulations

TRL 7: Full-scale prototype in clinical trials (Phase I, II, III), pilot production, market readiness, performance benchmarks, regulatory documentation preparation

TRL 8: Final product qualified through extensive testing and validation, approval submission

TRL 9: Full deployment, regulatory approval completion, commercial mass production, market entry and distribution, post-market monitoring, continuous improvement processes, long-term efficacy monitoring, life cycle management.

Regulatory considerations at each TRL stage:

e.g. risk-benefit assessment, clinical validation requirements, post-market surveillance, ethical approvals, patient safety considerations, cybersecurity integration, industry partnerships, funding models for device development, intellectual property considerations.

Challenges and barriers in TRL progression:

e.g. funding gaps; regulatory hurdles; clinical trial complexity; supply chain and manufacturing scalability; intellectual property (IP) and patenting; safety and risk assessment; user adoption challenges; compliance with ISO 13485, MDR, FDA QSR.

LO4 **Present an investigation of an identified medical device to an intended audience**

Device overview:

Device functionality: e.g. core components, user interface, integration with healthcare systems, automation levels

How it works: e.g. operation mechanisms, user steps, clinical applications, effectiveness

Failure risks: e.g. component degradation, cybersecurity vulnerabilities, incorrect usage, interoperability issues, failure modes, troubleshooting, safety protocols, user error

Device classification: e.g. different models, variations, alternatives, market options, emerging technologies; risk class, regulatory classification, industry applications, reimbursement models.

Comparative analysis:

Common features: e.g. materials used, power supply, connectivity (e.g. IoT-enabled, wireless capabilities), essential functions, user interface, regulatory compliance, safety measures

Differences among similar devices: e.g. market alternatives, unique selling points (USPs), advantages and limitations

Environmental impact: e.g. sustainability considerations, carbon footprint, material recyclability, disposal guidelines

Carbon footprint: e.g. manufacturing impact, material sustainability, usage, environmental impact

Lifespan: e.g. durability, maintenance, expected life, end-of-life disposal, recycling.

Presentation techniques and soft skills:

Data visualisation: e.g. graphs, charts, diagrams, models, slides, statistical analysis, performance benchmarks

Effective communication: e.g. clarity, conciseness, audience adaptation, technical language, audience engagement (e.g. interactive questioning, feedback incorporation, knowledge level adaptation), storytelling approach

Regulatory and compliance language: e.g. accuracy in claims, evidence-based justifications, citation of clinical trials

Soft skills: e.g. public speaking, body language, eye contact, professional demeanour

Equality, diversity and inclusion (EDI) considerations: demographic insights, cultural considerations, language preferences, technological literacy, representative imagery.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Review the different types of classification used for medical devices</td><td rowspan="2">D1 Evaluate, using a range of real-world examples, the effectiveness of the device classification categories on medical devices, considering the risks and benefits.</td></tr>
<tr><td>P1 Review, using a range of real-world examples, the different types of categories of medical devices.

P2 Discuss, using a range of real-world examples, the different classes of medical devices, including the risks and benefits.</td><td>M1 Analyse, using a range of real-world examples, the impact of the device classification categories on medical devices, considering the risks and benefits.</td></tr>
<tr><td colspan="2">LO2 Explore the stages of the product life cycle for medical devices</td><td rowspan="4">LO2 and LO3

D2 Evaluate the relationship between the different TRLs and the product life cycle for a range of medical devices.</td></tr>
<tr><td>P3 Explain the design and manufacturing stages of the product life cycle for a range of real-world medical devices.

P4 Explain the quality control, post-market surveillance and end-of-life stages of the product life cycle for a range of real-world medical devices.</td><td>M2 Justify, using a range of real-world medical devices, the effectiveness of the various stages of the product life cycle for medical devices.</td></tr>
<tr><td colspan="2">LO3 Explain the different technology readiness levels (TRLs) as applied to medical devices</td></tr>
<tr><td>P5 Explain, using a range of real-world examples, the different technology readiness levels (TRLs) as applied to medical devices.

P6 Discuss, using a range of real-world examples, the barriers to progression between the different TRLs, including the regulation considerations at each stage.</td><td>M3 Justify, using a range of real-world examples, the impact of different technology readiness levels (TRLs) in developing effective medical technology devices.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Present an investigation of an identified medical device to an intended audience		
P7 Develop a presentation containing the results of an investigation into an identified medical device for a specific clinical requirement. **P8** Present the results of the investigation into the MedTech device to an intended audience, obtaining a range of relevant feedback.	**M4** Analyse the results of the audience feedback on the presentation to identify a range of strengths and areas for improvement.	**D3** Evaluate the effectiveness of the presentation in communicating the findings of the investigation to the intended audience.

Recommended Resources

Textbooks

Bronzino, J.D. ed. (2006). *Medical Devices and Systems*. 1st Ed. Boca Raton: CRC Press.

Fries, R.C. (2012) *Reliable Design of Medical Devices*. 3rd Ed. Boca Raton: CRC Press.

Ogrodnik, P.J. (2019) *Medical Device Design: Innovation from Concept to Market*. London: Academic Press.

Weinger, M.B., Wiklund, M.E. and Gardner-Bonneau, D.J. eds. (2010) *Handbook of Human Factors in Medical Device Design*. 1st Ed. Boca Raton: CRC Press.

Wiklund, M.E., Kendler, J. and Strochlic, A.Y. (2015). *Usability Testing of Medical Devices.* 2nd Ed. Boca Raton: CRC Press

Websites

www://argondigital.com/blog/product-management/technology-readiness-levels-applied-to-medical-device-development/	Technology Readiness Levels applied to Medical Device Development (Blog)
www.devicelab.com/blog/what-is-the-medical-device-life-cycle/	What is the Medical Device Life Cycle? (Blog)
www.ema.europa.eu/en/human-regulatory-overview/medical-devices	Medical Devices (Resource)
www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom/chapter-2-classification	Consultation outcome Chapter 2: Classification (Article)
www://health.ec.europa.eu/document/download/cbb19821-a517-4e13-bf87-fdc6ddd1782e_en?filename=mdcg_2021-24_en.pdf	MDCG 2021-24 Guidance on classification of medical devices (Factsheet)
www://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf	Biomedical Technology Readiness Levels (Downloadable PDF)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 403: Risk Management (ISO 14971)

Unit 406: Regulatory Compliance

Unit 502: Computer Systems Validation

Unit 505: Manufacturing Processes

Unit 506: Understanding User Needs

Unit 507: DevOps Engineering

Unit 511: Hardware, Robotics and Autonomous Systems in MedTech

Unit 515: Advanced Manufacturing.

Unit 406: Regulatory Compliance

Unit code: **R/651/7104**

Unit level: **4**

Credit value: **15**

Introduction

Regulatory compliance is an essential component of the MedTech industry, ensuring that medical devices and technologies meet the highest standards of safety, efficiency and quality. As the MedTech landscape evolves with advancements in technology and innovation, the need for robust regulatory frameworks and compliance mechanisms continues to evolve as well. This unit is designed to provide students with an in-depth understanding of the regulatory requirements, frameworks and best practices that govern the MedTech sector. By studying this unit, students will gain the knowledge and skills necessary to understand the need for and the complexities of regulatory compliance within the MedTech sector.

The primary aim of this unit is to equip students with the core knowledge required to understand and apply regulatory compliance principles within the MedTech industry, culminating in the practical design of a standard operating procedure (SOP) for an identified MedTech scenario. This combination of theory and practical components will help students gain a comprehensive understanding of the regulatory environment and prepare them for real-world opportunities in the MedTech industry.

The unit covers a comprehensive range of topics essential for regulatory compliance in the MedTech industry. Topics include an overview of regulatory compliance fundamentals, the roles of various regulatory bodies, types of regulations, and the importance of compliance for patient safety and product effectiveness. Students will examine key regulatory frameworks such as the FDA, EMA, MHRA, and international standards such as ISO 13485 and ISO 14971. The unit also explores the rationale behind regulatory compliance, discussions about patient safety, product efficacy, legal requirements, ethical considerations, and the role of SOPs in medical device development. Each topic builds on the previous one, providing a progressive learning experience that prepares students for the complexities of regulatory compliance in MedTech.

On successful completion of this unit, students will have developed a robust set of theoretical knowledge and practical skills necessary for understanding regulatory compliance in the MedTech industry. These skills are directly relevant to various job roles in the MedTech sector, including Regulatory Affairs Specialist, Quality Assurance Manager, Compliance Officer and Product Development professional. After studying this unit, students will be well equipped to contribute to the development of safe, effective and compliant medical technologies in the MedTech industry.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explain the core concepts and terminology of MedTech regulations

LO2 Review the key regulatory frameworks that cover MedTech applications

LO3 Discuss the rationale behind regulation compliance and standard operating procedures (SOPs)

LO4 Develop a regulatory-compliant standard operating procedure (SOP) for an identified scenario in the MedTech sector.

Essential Content

LO1 **Explain the core concepts and terminology of MedTech regulations**

Regulatory compliance fundamentals:

Regulatory frameworks: legal requirements, enforcement mechanisms, compliance obligations, international treaties

Regulatory bodies: e.g. FDA (USA), EMA (EU), MHRA (UK), TGA (Australia), Health Canada, IMDRF, WHO

Types of regulations: pre-market approval, post-market surveillance, clinical investigation rules, cybersecurity guidelines

Importance of compliance: e.g. patient safety, liability and product effectiveness; efficacy assurance, risk management, ethical considerations, quality control

Global standardisation of medical devices: e.g. Global Harmonisation Task Force (GHTF), International Medical Device Regulators Forum (IMDRF), EU–US Mutual Recognition Agreements (MRAs)

Compliance examples: data integrity and cybersecurity, e.g. FDA 21 CFR Part 11, EU Annex 11, HIPAA, GDPR, Medical Device Cybersecurity Guidelines (MDCG 2019–16), NIS2 Directive

Clinical evidence requirements: e.g. clinical evaluation reports (CERs), real-world evidence (RWE), investigational device exemptions (IDEs), post-market clinical follow-up (PMCF)

Post-market surveillance: e.g. adverse event reporting, vigilance system, field safety corrective actions (FSCA), periodic safety update reports (PSUR)

Types of regulations: pre-market approval, post-market surveillance, clinical investigation rules, cybersecurity guidelines.

Key terms and concepts:

Key regulatory concepts: Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), risk-based classification

Regulatory requirements: safety, efficacy, risk management, conformity

Notified body: quality assurance, regulatory oversight, certification

Conformity: e.g. adherence, quality management system (QMS) compliance, policies, procedures, recording and reporting

Non-conformities: e.g. deviations (including documentation, process, practice), standards breaches, corrective actions

Regulatory approval: e.g. evaluation, confirmation, market access, adherence to required standards

Classification: e.g. risk levels and profile, class I (low risk), class II (medium risk), class III (high risk)

Gap analysis: current state versus required standards, mitigation actions

Clinical safety report: literature review (including usual practice, clinical impact assessment)

Hazard and risk assessment: e.g. methodologies, potential safety issues, risk identification, recording/reporting, risk mitigation; risk register matrix (e.g. qualifying, quantifying and mitigation)

Adverse events: CAPA (corrective and preventive actions), incident recording, risk profile analysis, incident reporting to relevant bodies, risk management, post-market surveillance

Compliance: adherence, regulatory adherence, enforcement, notified bodies

Post-market surveillance: monitoring after launch (e.g. device safety, effectiveness; report gathering methods).

LO2 **Review the key regulatory frameworks that cover MedTech applications**

Medical Device Regulation (MDR) fundamentals:

Successor of Medical Device Directive (MDD): transition, updated standards, compliance timeline

Coverage: all medical devices, territories, comprehensive scope

Responsibilities: manufacturers, supply chain accountability, audit requirements; notified body limitations; compliance deadline December 2028

Impact: product validation, market readiness, regulatory gaps

Global comparison: e.g. MDR versus other regulations, regional differences, commonalities

Practical implications: e.g. registration with notified bodies, appointment of UK Responsible Person for non-UK manufacturers.

IVDR (In Vitro Diagnostic Regulation) fundamentals:

Successor of In Vitro Diagnostic Directive (IVDD): transition, compliance updates, new standards

Coverage: in vitro diagnostic devices, territories, exhaustive application; expanded risk-based classification

Compliance: continuous updating, risk evaluation, stringent manufacturer requirements, including clinical evidence, post-market surveillance

Impact: product validation, compliance gaps, market distribution

Global comparison: IVDR versus other regulations, nuances, similarities.

Regional regulatory authorities:

FDA (USA): US regulations, Code of Federal Regulations (CFR)

EMA (European Union): EU regulations, Medical Device Coordination Group (MDCG)

MHRA (United Kingdom): UK regulations, Medicines and Healthcare products Regulatory Agency

TGA (Australia): Australian regulations, Therapeutic Goods Administration.

International standards:

ISO standards: ISO 13485 (QMS), ISO 14971 (risk management), ISO 9001 (quality management); integration with MDR/IVDR.

LO3 **Discuss the rationale behind regulation compliance and standard operating procedures (SOPs)**

Rationale behind regulation compliance:

Patient safety: e.g. harm reduction, safety measures, patient rights

Product efficacy: e.g. intended use, performance standards, clinical outcomes

Legal requirements: e.g. national laws, international standards, compliance mandates, adoption of new technologies, data safety requirements

Ethical considerations: e.g. corporate responsibility, public trust, ethical sourcing

Market access: e.g. regulatory approval, global markets, competitive advantage

Brand reputation: e.g. quality perception, brand integrity, consumer confidence

Risk management: risk identification, mitigation strategies, continuous monitoring.

Regulation evolution:

Technology advances: e.g. innovation, new device classes, e-health integration

Adverse event reporting: e.g. real-world data, post-market analysis, feedback loops

Regulatory bodies and standards: e.g. MHRA, FDA, ISO 13485, ISO 14971.

Demonstrating compliance:

Audits: e.g. internal audits, external audits, preparation and compliance, comparison

Quality management systems (QMS): e.g. requirements, legislation, MDR and IVDR

Corrective and preventive actions (CAPA), risk management, documentation, reporting.

The importance of standard operating procedures for regulatory compliance:

Consistency and reliability: standardised practices, e.g. uniform procedures, consistency across teams, process standardisation

Minimised variability: e.g. reduced human error, consistent outcomes, controlled processes

Quality assurance: e.g. high-quality standards, reliable performance, product integrity

Compliance requirements: e.g. regulatory frameworks adherence, legal obligations, mandatory standards

Audit readiness: e.g. compliance inspections, regulatory audits, inspection preparedness

Documentation and evidence: e.g. record keeping, regulatory submission support, compliance evidence

Risk identification: e.g. hazard analysis, risk assessments, potential risk identification

Risk mitigation strategies: e.g. control measures, preventive actions, mitigation plans

Incident response preparedness: e.g. crisis management, quick response protocols, preventive contingencies

Process clarity: e.g. clear workflow, step-by-step instructions, defined activities

Training and onboarding: e.g. employee training programmes, onboarding new staff, skill development

Continuous improvement: e.g. process evaluation, performance metrics, feedback incorporation

Legal protection: e.g. regulatory defence, regulatory justification, compliance evidence, legal safeguards

Dispute resolution: e.g. conflict mitigation, dispute records, problem-solving framework

Litigation mitigation: e.g. legal risk reduction, compliance assurance, legal safety net.

LO4 **Develop a regulatory-compliant standard operating procedure (SOP) for an identified scenario in the MedTech sector**

SOP title and identification:

SOP title: clear and descriptive, unique identifier, relevant to the process

Document number: unique reference code, version control, revision history

Effective date: implementation date, validity period, expiration details

Approval and authorisation: sign-off by responsible personnel, regulatory compliance verification, designated authority.

Purpose and scope:

Objective: e.g. procedure goals, process rationale, alignment with regulatory requirements, intended outcomes

Applicability: e.g. relevant departments, personnel roles, operational areas

Regulatory and compliance references: e.g. FDA, EU MDR, ISO 13485, Good Manufacturing Practice (GMP), industry standards

Exclusions and limitations: e.g. scope restrictions, process boundaries, specific exemptions.

Roles and responsibilities:

Process owners: e.g. responsible individuals, accountability structure, key decision-makers

Personnel involvement: e.g. Operators, quality assurance (QA) teams, Auditors, Regulatory Affairs Specialists

Training requirements: e.g. competency assessment, certification prerequisites, knowledge reinforcement

Communication channels: e.g. reporting hierarchy, feedback mechanisms, escalation procedures.

Procedure and methodology:

Step-by-step instructions: e.g. sequential breakdown, required actions, defined input/output

Equipment and materials: e.g. required tools, calibration needs, approved suppliers

Process controls: e.g. risk mitigation measures, critical control points, monitoring requirements

Data management: e.g. record keeping, electronic logging, data integrity protocols.

Documentation and record keeping:

Forms and templates: e.g. standardised formats, regulatory-approved layouts, predefined fields

Data entry protocols: e.g. electronic versus manual logging, secure storage, retrieval procedures

Audit trails: e.g. change tracking, version history, electronic signatures, record keeping, archival process

Archival and retention policies: e.g. storage duration, disposal requirements, access restrictions

Process diagrams: e.g. flowcharts, visual workflow, process mapping.

Compliance and monitoring:

Compliance guidelines: e.g. regulatory requirements, conformance criteria, standards compliance

Monitoring mechanisms: e.g. compliance checks, performance metrics, continuous improvement

Review and audits: e.g. internal audits, compliance reviews, periodic evaluation, audit preparation, document control, compliance evidence.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explain the core concepts and terminology of MedTech regulations</td><td rowspan="5">LO1 and LO2

D1 Evaluate, using a range of real-world examples, the impact of MedTech regulations and regulatory frameworks on the development of medical devices.</td></tr>
<tr><td>P1 Explain, using a range of real-world examples, the fundamental principles of regulation compliance in MedTech.

P2 Discuss, using a range of real-world examples, the key terms and concepts of MedTech regulations.</td><td>M1 Analyse, using a range of real-world examples, the core concepts and terminology of MedTech regulations.</td></tr>
<tr><td colspan="2">LO2 Review the key regulatory frameworks that cover MedTech applications</td></tr>
<tr><td>P3 Explain, using a range of real-world examples, the relevant legislation that covers MedTech applications.

P4 Review, using a range of real-world examples, the relevant regulatory authorities and standards that cover MedTech applications.</td><td>M2 Assess, using a range of real-world medical devices, the key regulatory frameworks that cover MedTech applications.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Discuss the rationale behind regulation compliance and standard operating procedures (SOPs)		**LO3 and LO4** **D2** Evaluate the effectiveness of the designed SOP in how well it aligns with the identified objectives of the MedTech scenario and complies with any relevant regulations.
P5 Discuss, using a range of real-world examples, the evolution and rationale behind regulation compliance for medical devices. **P6** Review, using a range of real-world examples, the rationale behind having standard operating procedures for medical devices.	**M3** Analyse, using a range of real-world examples, the rationale behind regulation compliance and Standard Operating Procedures (SOPs) for medical devices.	
LO4 Develop a regulatory-compliant standard operating procedure (SOP) for an identified scenario in the MedTech sector		
P7 Design a regulatory-compliant SOP for an identified scenario within the MedTech sector. **P8** Review the developed regulatory-compliant SOP methodology with a variety of key stakeholders to identify a range of strengths, weaknesses and areas for improvement.	**M4** Analyse, using the contents of the stakeholder review, the choices made in the development of the SOP methodology for an identified MedTech scenario.	

Recommended Resources

Textbooks

Cohen, I.G., Minssen, T., Price II, W.N., Robertson, C. and Shachar, C. eds. (2022). *The Future of Medical Device Regulation: Innovation and Protection.* Cambridge: Cambridge University Press.

Donzé, P.Y. (2022) *Medtech*. Singapore: Springer Singapore.

Fiedler, B.A. ed. (2016). *Managing Medical Devices within a Regulatory Framework*. Amsterdam: Elsevier.

Madir, J. ed. (2020) *HealthTech: Law and Regulation*. Cheltenham: Edward Elgar Publishing.

Srinivasan Timiri Shanmugam, P. ed. (2022) *Medical Devices: A Practical Guide*. 1st ed. Boca Raton: CRC Press.

Stothart, C. (2022) *Motivation: The Ultimate Guide to Leading your Team*. Abingdon: Routledge.

Vettraino, E., and Urzelai, B. eds. (2021) *Team Academy: Leadership and Teams*. 1st Ed. New York: Routledge.

Wong, J. and Tong, R.K. eds. (2022) *Medical Regulatory Affairs: An International Handbook for Medical Devices and Healthcare Products*. Boca Raton: CRC Press.

Websites

www.ema.europa.eu/en/human-regulatory-overview/medical-devices	Medical devices (Resource)
www://euivdr.com/	Regulation (EU) 2017/746 (EU IVDR) (Resource)
www://eumdr.com/	Regulation (EU) 2017/745 (EU MDR) (Resource)
www.fda.gov/	US Food & Drug Administration (TGA) (Resource)
www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/quality-and-compliance-medical-devices	Quality and Compliance (Medical Devices) (Resource)
www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency	Medicines & Healthcare products Regulatory Agency (Resource)

www.gov.uk/guidance/regulating-medical-devices-in-the-uk	Regulating medical devices in the UK (Resource)
www.greenlight.guru/blog/how-to-write-effective-sops-for-medical-devices	How to Write Effective SOPs for Medical Devices (Blog)
www.greenlight.guru/blog/medical-device-compliance	Medical Device Compliance: Regulations, Standards, and Solutions (Blog)
www.greenlight.guru/glossary/standard-operating-procedure-for-medical	Standard Operating Procedure for Medical Devices (Blog)
www.tga.gov.au/	Therapeutic Goods Administration (TGA) (Resource)

Links

This unit links to the following related units:

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 501: Data Management and Cybersecurity

Unit 502: Computer Systems Validation

Unit 508: Professional Development

Unit 509: ISO Standard Auditing for Medical Devices

Unit 513: Quality by Design.

Unit 407: Software and UI/UX Design

Unit code: **T/651/7105**

Unit level: **4**

Credit value: **15**

Introduction

The fusion of technology and medical expertise is driving innovations in medical technology that enhance the quality of healthcare. This unit aims to equip students with critical skills to plan and design intuitive, user-centred interfaces and to develop effective interfaces for medical applications. This unit is essential for aspiring MedTech developers and designers, focusing on creating user interfaces (UI) and user experiences (UX) that improve the usability and efficiency of MedTech systems.

The primary aim of this unit is to provide students with the core theory of UI/UX design within the context of a MedTech application. Students will first review the different software development methodologies that can be used to create a MedTech application. They will go on to explore the principles underpinning an effective UI design and understand the significance of UX in MedTech systems. By the end of this unit, students will have the competency to develop comprehensive UI/UX solutions tailored for the medical field.

This unit covers a wide range of essential topics, beginning with the fundamental principles and theories of the software development life cycle and a range of relevant methodologies. The unit will then cover the core theories of UI design specific to MedTech systems, such as consistency, clarity and accessibility. It will explore UX design elements crucial for healthcare scenarios, including cognitive load management and emotional design. The unit concludes with the development of an effective prototype UI/UX for a specified MedTech scenario, emphasising the principles of scenario analysis, iterative design and rigorous testing.

On successful completion of this unit, students will have obtained an understanding in the creation of effective user-centred interfaces. They will be able to apply UI and UX design principles to real-world medical applications, ensuring usability, efficiency and compliance with regulatory standards. These skills are directly applicable to careers such as MedTech UI/UX Designer, Healthcare Application Developer, Interaction Designer and Medical Software Engineer.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explore the range of software development methodologies that can be used in developing MedTech applications

LO2 Explain the principles of user interface (UI) design used in MedTech systems

LO3 Review the concepts of user experience (UX) design used in MedTech systems

LO4 Develop an effective UI/UX prototype for an identified MedTech scenario.

Essential Content

LO1 **Explore the range of software development methodologies that can be used in developing MedTech applications**

Definition and characteristics:

Software development methodologies: frameworks for structuring, planning and controlling software development processes

Core characteristics: process-driven, structured phases, defined roles, iterative or sequential workflows, quality assurance focus

Key components: requirement gathering, system design, implementation, testing, deployment, maintenance

Development approaches: predictive (predefined planning), adaptive (flexible, iterative changes)

Roles and responsibilities: e.g. Analyst (Business, Systems), Designers (Technical Architect, Design Engineer, UI/UX), Development (Development Lead, Team Leader, Senior Developer/Programmer, Developer/Programmer), Testers (QA Test Lead, QA Test), Deployment (DevOps engineer, IT Technician); interactions (teams, individuals).

Types of software development methodologies:

Waterfall methodology: structure: linear, sequential, phase-based; phases: requirement analysis, system design, implementation, testing, deployment, maintenance; documentation: extensive, regulatory-focused, detailed process guidelines; best use cases: compliance-heavy projects, long-term development, medical device software validation

Agile methodology: structure: Iterative, incremental, adaptive; frameworks: Scrum, Kanban, extreme programming (XP), feature-driven development (FDD); key components: sprints, backlog management, continuous integration, frequent stakeholder collaboration; best use cases: rapid prototyping, evolving MedTech applications, AI-driven healthcare solutions

Scrum framework: team roles: Scrum master, product owner, development team; work cycle: sprint planning, daily stand-ups, sprint review, retrospective; benefits: rapid iterations, high adaptability, continuous improvement

DevOps methodology: integration: development and operations collaboration, continuous deployment, automation; key components: CI/CD pipelines, automated testing, infrastructure as code (IaC); best use cases: cloud-based medical platforms, real-time health monitoring software, data security compliance

Life cycle types: e.g. linear, iterative, hybrid, differences, comparative benefits.

Application of software development methodologies in MedTech:

Regulatory compliance and quality assurance

Standards alignment: e.g. IEC 62304 (medical software life cycle), ISO 13485 (quality management), FDA guidelines; MHRC

Risk-based development: e.g. waterfall for documentation-heavy compliance, agile for continuous risk assessment

User-centred design and iterative development: e.g. clinical workflow optimisation (e.g. agile and Scrum for real-time user feedback, usability testing cycles); medical device usability standards (e.g. human factors engineering, accessibility considerations, interface responsiveness).

LO2 **Explain the principles of user interface (UI) design used in MedTech systems**

UI design principles:

Consistency: e.g. uniform layout, colour schemes, colour theory, typography, iconography, input fields, response behaviours

Clarity: e.g. legible fonts, high contrast, unambiguous labels, intuitive navigation, structured content hierarchy

Feedback and responsiveness: e.g. haptic feedback, audio cues, animation indicators, loading spinners, progress bars

Efficiency and accessibility: e.g. quick access controls, keyboard shortcuts, voice recognition, touch gestures, one-hand operation optimisation

Error prevention and recovery: e.g. undo options, auto-save functionality, predictive text, confirmation dialogues, input validation warnings.

UI components and elements in MedTech applications:

Navigation elements: e.g.

- menus, e.g. dropdown, hamburger, side navigation, tabbed navigation, radial menus, hierarchical navigation structures
- Breadcrumbs, e.g. step-based process indicators, workflow progress tracking, sequential navigation aids
- Toolbars, e.g. context-sensitive action bars, floating toolbars, pinned command strips
- navigation drawers, e.g. expandable panels, categorised menus, collapsible sections
- tabs and section dividers, e.g. multi-view switching, categorised sections, form segmentation

Input controls: e.g.

- buttons, e.g. primary actions, secondary actions, floating action buttons (FABs), toggle buttons, icon-based button
- sliders and dials, e.g. volume control, intensity adjustment, zoom control, brightness tuning, dosage selection
- switches and toggles, e.g. binary options, settings controls, privacy toggles, dark mode activation
- dropdown lists, e.g. predefined selections, multi-select dropdowns, predictive dropdowns
- checkboxes and radio buttons, e.g. multi-option selections, single-choice selections, condition-based inputs
- text fields, e.g. single-line input, multi-line input, numeric input, password fields, masked input fields
- date and time pickers, e.g. calendar views, clock selectors, duration selectors, scheduling controls
- signature capture fields, e.g. digital ink signature areas, biometric signature inputs, stylus-supported signature pads

Data display elements: e.g.

- labels and tags, e.g. status indicators, classification tags, data labelling for differentiation
- icons and symbol sets, e.g. standardised medical symbols, notification badges, interactive icons
- tables and grids, e.g. patient data tables, medical records dashboards, real-time monitoring grids
- cards and containers, e.g. grouped information blocks, interactive summaries, modular data sections
- lists and repeater views, e.g. dynamic content loading, scrollable record sets, infinite scroll lists
- data visualisation elements, e.g. line graphs, bar charts, pie charts, scatter plots, heat maps, waveform displays (ECG, EEG)
- real-time data feeds, e.g. live vital signs monitoring, streaming telemetry data, auto-updating status panels

User interaction and control elements: e.g.

- touch and gesture controls, e.g. multi-touch gestures, swipe interactions, pinch-to-zoom, long press actions
- virtual keyboards, e.g. on-screen keyboard layouts, numeric keypads, specialised medical symbol keyboards

voice commands and speech recognition, e.g. hands-free operation, voice-controlled navigation, dictation input

camera-based interactions, e.g. QR code scanning, barcode recognition, image-based diagnosis input

biometric authentication and controls, e.g. fingerprint scanning, facial recognition, retinal scanning, vein pattern authentication

UI components for large displays and diagnostic equipment: e.g.

interactive dashboards, e.g. multi-panel layouts, modular widgets, AI-assisted diagnostic suggestions

3D visualisations and models, e.g. MRI scan visualisation, CT scan image manipulation, anatomical overlays

split-screen and multi-view interfaces, e.g. dual-panel workflows, synchronised comparative imaging, doctor–patient co-viewing displays

context-aware interfaces, e.g. smart layouts that adjust based on user role, patient status or device connection

remote monitoring interfaces, e.g. secure data streaming, cloud-based data sync, multi-location access controls.

Regulatory compliance:

FDA, MHRA, IEC 62366, ISO 9241 for medical device usability, data security, user safety.

LO3 **Review the concepts of user experience (UX) design used in MedTech systems**

Fundamental UX design concepts:

User-centred design: e.g. patient needs, clinician workflows, accessibility considerations, inclusivity, intuitive interfaces

Cognitive load management: e.g. simplified workflows, minimal distractions, progressive disclosure, chunking of information

Interaction design: e.g. seamless transitions, natural gestures, consistent response timing, micro-interactions

Efficiency and task optimisation:, e.g. reduced cognitive strain, shortcut actions, guided processes, auto-complete functionality

Emotional and psychological design: e.g. trust building, stress reduction, visual reassurance, predictability in behaviour.

UX components and elements in MedTech applications:

Navigation and workflow optimisation: e.g.

- task-based navigation, e.g. step-by-step guides, intuitive sequencing, adaptive task prioritisation
- breadcrumb trails and path awareness, e.g. location indicators, forward/backward navigation, process tracking
- dashboard customisation, e.g. role-specific layouts, adjustable widget placement, real-time data updates
- navigation flow, e.g. logical movement between screens, easy return options, multi-access pathways
- hierarchy awareness, e.g. parent–child relationships, progressive drilldowns, structured menus

Psychological and cognitive factors in UX: e.g.

- cognitive load reduction, e.g. streamlined decision-making, removal of redundant steps, automatic data population
- attention management, e.g. contrast-based focal points, animated guidance, colour-coded urgency markers
- human error prevention, e.g. confirmation dialogues, predictive text, error-tolerant interfaces, default-safe choices
- decision fatigue prevention, e.g. limited options per screen, progressive question sets, assisted recommendations
- anxiety and stress reduction, e.g. soft colour palettes, reassuring micro-copy, real-time patient condition updates

Medical context considerations: e.g.

- critical situation readiness, e.g. quick-action buttons, large readable fonts, minimalistic emergency modes
- assistive technologies integration, e.g. screen readers, eye-tracking controls, adaptive UI for motor impairments
- doctor–patient interaction support, e.g. real-time collaboration tools, co-browsing interfaces, AI-powered decision assistance
- remote healthcare and telemedicine UX, e.g. real-time video calls, synchronised data sharing, latency-aware interactions

Medical data visualisation: e.g.

- dynamic charts, waveform analysis, multi-layer data representation

Feedback and validation in UX: e.g.

immediate system feedback, e.g. loading indicators, transition animations, step confirmations

UX performance metrics, e.g. task completion rate, error frequency, user satisfaction scores, engagement duration

A/B testing and iteration, e.g. side-by-side UX comparisons, usability analytics, iterative improvements

personalisation and adaptability, e.g. user preference settings, customisable layouts, adaptive interface behaviour

post-use support and education, e.g. guided tutorials, onboarding checklists, interactive troubleshooting.

LO4 **Develop an effective UI/UX prototype for an identified MedTech scenario**

Scenario analysis:

User needs assessment, clinical workflow integration, stakeholder expectations, accessibility requirements, regulatory constraints, data security considerations.

UI/UX design:

Strategies: e.g. mood boards, iterative testing, feedback incorporation, agile development methodologies, house styles (e.g. client requirements, colour scheme, font family, logos)

Wireframing: e.g. low-fidelity sketches, mid-fidelity wireframes, high-fidelity wireframes

Interactive prototypes: e.g. clickable layouts, interactive elements, user flow simulations/use cases, activity diagrams

Design documentation: e.g. annotated wireframing, style guides, component libraries, UML (e.g. data flow diagrams, sequence diagrams, structure diagrams), code design (e.g. pseudocode, structured English, flowcharts, decision trees).

Development of the solution:

Code structuring, UI responsiveness, accessibility compliance, internationalisation, multi-platform adaptation

Code techniques: e.g. code standards, comments, modules, source control.

Functional testing of the UI:

Functional testing: e.g. verification and validation (V&V), test scenarios, test types (including unit, integration, regression), test automation, fault tolerance prototype evaluation.

Usability testing of the UX:

Testing methods: e.g. usability testing sessions, formative testing, summative testing, A/B testing, remote usability testing, heuristic evaluation (e.g. expert review using usability principles such as Jakob Nielsen's heuristics, ISO 9241 guidelines), identification of interface inconsistencies (e.g. navigation inefficiencies, cognitive overload), cognitive walkthrough, compliance verification, usability benchmarking, bug tracking, eye tracking and biometrics, think-aloud protocol

Performance metrics: e.g. user satisfaction, error rate, efficiency improvements, adoption rate, response time, task success rate

Stakeholder feedback: e.g. verbal, survey, questionnaire, meetings, prototype demonstration

Test outcomes: e.g. interface refinement, workflow optimisation, error reduction strategies (e.g. warning messages, prompts, feedback loops), accessibility enhancement, training and documentation.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explore the range of software development methodologies that can be used in developing MedTech applications</td><td rowspan="2">D1 Evaluate the effectiveness of an identified software development methodology in the development of a real-world MedTech application.</td></tr>
<tr><td>P1 Explore the definition, characteristics and job roles of a range of software development methodologies that can be used in developing MedTech applications.

P2 Review the range of software development methodologies that can be used in developing MedTech applications.</td><td>M1 Analyse the effectiveness of the range of software development methodologies that can be used in developing MedTech applications.</td></tr>
<tr><td colspan="2">LO2 Explain the principles of user interface (UI) design used in MedTech systems</td><td rowspan="4">LO2 and LO3

D2 Evaluate the effectiveness of the UI and UX design in an identified, real-world MedTech system.</td></tr>
<tr><td>P3 Explain, using a range of real-world case studies, the principles of user interface (UI) design in MedTech systems.

P4 Discuss, using real-world examples, the application of a range of UI components in a variety of MedTech systems.</td><td>M2 Analyse the effectiveness of the UI design and UI component selection for a range of real-world MedTech systems.</td></tr>
<tr><td colspan="2">LO3 Review the concepts of user experience (UX) design used in MedTech systems</td></tr>
<tr><td>P5 Review, using a range of real-world case studies, the principles of user experience (UX) design in MedTech systems.

P6 Examine, using real-world examples, the application of a range of UX components in a variety of MedTech systems.</td><td>M3 Analyse the effectiveness of the UX design and UX component selection for a range of real-world MedTech systems.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Develop an effective UI/UX prototype for an identified MedTech scenario		
P7 Design an effective UI/UX solution for an identified MedTech scenario. **P8** Develop an effective UI/UX solution based on the identified UI/UX design for an identified MedTech scenario. **P9** Carry out UI and UX testing on the developed solution based on the identified UI/UX design for the identified MedTech scenario.	**M4** Optimise the developed solution based on the results of the UI/UX testing and stakeholder feedback.	**D3** Justify the decisions made in the development of the UI/UX solution for the identified scenario, demonstrating how the decisions led to an effective solution.

Recommended Resources

Textbooks

Bodker, S. (2021) *Through the Interface: A Human Activity Approach to User Interface Design*. Boca Raton: CRC Press.

Gothelf, J. and Seiden, J. (2021) *Lean UX: Designing Great Products with Agile Teams*. Sebastopol CA: O'Reilly Media, Inc.

Hartson, R. and Pyla, P.S. (2018) *The UX Book: Agile UX Design for a Quality User Experience*. Cambridge, MA: Morgan Kaufmann.

Laplante, P.A. and Kassab, M. (2022) *What Every Engineer Should Know About Software Engineering.* Boca Raton: CRC Press.

Levy, J. (2021) *UX Strategy*. Sebastopol CA: O'Reilly Media, Inc.

Unger, R. and Chandler, C. (2023) *A Project Guide to UX Design: For User Experience Designers in the Field or in the Making.* Berkeley CA: New Riders.

Yablonski, J. (2024) *Laws of UX*. Sebastopol CA: O'Reilly Media, Inc.

Websites

www.calibraint.com/blog/ui-ux-design-elements	Mastering The Art Of UI/UX Design Elements: A Quick Guide! (Blog)
www.geeksforgeeks.org/5-most-commonly-used-software-development-methodologies/	5 Most Commonly used Software Development Methodologies (Article)
www.geeksforgeeks.org/software-development-life-cycle-sdlc/	Software Development Life Cycle (SDLC) (Article)
www://lawsofux.com/	Laws of UX (General reference)
www.theknowledgeacademy.com/blog/ui-design-principles/	9 Key UI Design Principles You Need to Know About (Blog)
www.uxdesigninstitute.com/blog/ux-design-principles/	7 fundamental user experience (UX) design principles all designers should know (2024) (Article)

www.uxpin.com/studio/blog/ui-design-principles/	The Basic Principles of User Interface Design (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 404: Applied Programming

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 501: Data Management and Cybersecurity

Unit 506: Understanding User Needs

Unit 507: DevOps Engineering

Unit 513: Quality by Design.

Unit 408: Designing a MedTech Project (Pearson Set)

Unit code: **Y/651/7106**

Unit level: **4**

Credit value: **15**

Introduction

This unit is assessed through a Pearson-set assignment. The project brief will be set by the centre, based on a theme provided by Pearson (this will change annually). The theme and chosen project within the theme will enable students to explore and examine a relevant and topical aspect of MedTech in the context of a professional environment.

The design process is a fundamental aspect of developing effective MedTech projects. Understanding the various methodologies, tools and techniques involved in design allows MedTech professionals to create informed, data-driven solutions to complex issues. This unit is designed to provide students with a comprehensive understanding of the design process, from the initial stages of project planning to the presentation of findings. By exploring different design methodologies and their applications, students will be equipped to develop and present solutions that address specific MedTech project briefs.

The aim of this unit is to give students an opportunity to demonstrate the skills required for developing a design based on the requirements of a MedTech scenario as well as to show the ability to use data and evidence to inform decisions. Students will undertake independent research and investigation of a theme set by Pearson. Based on these findings, students will use the outcomes to produce designs for a MedTech brief that will then be presented with justifications.

On successful completion of this unit, students will have the ability to engage in decision-making, research and design activities and project-planning tasks. They will have the fundamental knowledge and skills that will enable them to investigate and analyse MedTech concepts, and engage with stakeholders in a work-related, professional context to determine appropriate outcomes and solutions. In addition, students will have gained the confidence to present their findings to a target audience, using a range of professional and technical presentation techniques. These skills are directly linked to roles such as Project Managers, Data Analysts and Project Designers.

***Please refer to the accompanying Pearson-set Assignment Guide and the Theme Release document for further support and guidance on the delivery of the Pearson-set unit.**

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Conduct small-scale research in relation to a given MedTech project brief

LO2 Develop a design based on the requirements of a given MedTech project brief

LO3 Present the design recommendations to an intended audience

LO4 Refine the design based on stakeholder feedback.

Essential Content

LO1 **Conduct small-scale research in relation to a given MedTech project brief**

User needs identification:

Engaging with healthcare professionals, patients and stakeholders to define requirements, intended use, environmental conditions and constraints.

Research methods, tools and techniques:

Primary research: e.g. interviews, focus groups, surveys, direct observation

Secondary research: e.g. academic journals, industry reports, regulatory guidelines

Existing datasets: e.g. public health databases, clinical databases

Healthcare records: e.g. electronic health records, patient registries

Market reports: e.g. industry analyses, sales data

Systematic reviews: literature review (e.g. database searches, inclusion criteria); meta-analysis review (e.g. effect size calculations, heterogeneity assessment); scoping reviews (e.g. mapping existing literature, identifying gaps).

Data collection techniques:

Quantitative: e.g. statistical data, patient outcomes, trial results; surveys (e.g. questionnaire design, sampling techniques); data analytics (e.g. statistical methods, data visualisation)

Qualitative: e.g. user experience, clinician feedback; interviews (e.g. semi-structured, structured, unstructured); focus groups (e.g. facilitation techniques, group dynamics); case studies (e.g. in-depth analysis, case selection criteria)

Stakeholder analysis and mapping: identifying key decision-makers (e.g. clinicians, regulatory bodies, manufacturers, patients); stakeholder influence and impact assessment.

Ethical and legal considerations:

Data protection regulations (GDPR, HIPAA), informed consent, patient confidentiality, intellectual property rights

Behaviours: ethical (e.g. transparency, integrity, honesty, responsibility, legislative compliance); inclusive (e.g. diversity, accessibility, collaboration, equity); personal (e.g. flexibility, adaptability, accountability, task ownership); professional (e.g. integrity, honesty, confidentiality).

Use of data analytics:

Predictive modelling, risk analysis, real-time monitoring systems, AI-driven diagnostics, trend analysis, risk assessment tools, healthcare informatics applications.

LO2 **Develop a design based on the requirements of a given MedTech project brief**

Project requirements:

Cost analysis, resource planning, regulatory impact assessment, market demand evaluation; feasibility analysis ; task and dependancies scheduling

Functional requirements: performance (e.g. speed, accuracy, reliability); usability (e.g. user interfaces, ease of use); scalability (e.g. expandability, adaptability)

Project Context: PESTLE (political, economic, social, technological, legal, environmental); SWOT (strength, weakness, opportunities, threats); VUCA (velocity, uncertainty, complexity, ambiguity)

Project governance structure: e.g. requirements, process, impact, needs and benefits

Business case: e.g. maintenance, purpose, content, importance, context, relevance, benefits; organisational alignment

Project structures: e.g. functional, matrix, project, differences, comparative benefits

Project life cycles: linear, iterative

Organisational strategies: portfolio (e.g. definition, strategy, balance, evaluation); programme (e.g. definition, coordination, governance, benefits); project (e.g. scope, resources, time, deliverables); interdependencies (e.g. communication, decision-making, risk management).

Design methodologies:

Agile development, iterative prototyping, systems engineering approaches

Conceptual design and Ideation: e.g. brainstorming sessions, design thinking, rapid prototyping, feasibility assessment

Preliminary prototyping: e.g. low-fidelity prototypes, early-stage usability testing, feedback collection

Detailed engineering design: e.g. CAD modelling, material selection, system architecture, software/hardware integration

Design criteria: specifications (e.g. technical details, design parameters); constraints (e.g. constraints identification, limitations analysis); standards (e.g. medical device standards, industry benchmarks).

Technical considerations:

Software versus hardware solutions, system interoperability, cybersecurity, cloud-based applications.

Compliance and risk management:

Risk management and compliance: ISO 13485, FDA/MHRA regulations, EU MDR, IEC 62304 (software life cycle processes), risk management strategies (FMEA, HACCP).

Sustainability and scalability:

Environmental impact, manufacturing feasibility, life cycle considerations, budget constraints, cost–benefit analysis

Objectives: impact, challenges, net carbon zero (UK Government).

LO3 **Present the design recommendations to an intended audience**

Presentation techniques:

Verbal presentations, technical reports, pitch decks, digital prototypes, formal pitch presentations, investor meetings, business case documentation

Presentation skills: public speaking (e.g. speech delivery, audience engagement); storytelling (e.g. narrative structure, emotional connection)

Equality, diversity and inclusion (EDI) considerations: e.g. age demographics, cultural context, language options, tech proficiency, content alignment, appropriate visual elements.

Data visualisation and communication:

Visual aids: e.g. graphs, heatmaps, UI/UX wireframes, CAD models, regulatory documentation, charts, dashboards, medical device schematics, software UI/UX wireframes; slides (e.g. layout, design principles)

Software: e.g. PowerPoint (e.g. presentation design, animation effects), Prezi (e.g. dynamic presentations, zooming user interface), Keynote (e.g. Apple presentation software, design features).

Justification of design decisions:

e.g. cost–benefit analysis, risk mitigation strategies, stakeholder alignment, competitive benchmarking, cost-effectiveness analysis, clinical validation, usability testing results, regulatory impact assessment.

Audience awareness and impact:

Tailoring presentations to specialists (e.g. engineers, investors) versus non-specialists (e.g. patients, policymakers)

Audience analysis: e.g. knowledge levels (e.g. technical expertise, background knowledge), interest areas (e.g. relevance, audience priorities).

LO4 **Refine the design based on stakeholder feedback**

Review and refinement:

Peer feedback, expert validation, performance testing, design iteration cycles

Feedback mechanisms including interactive sessions: Q&A (e.g. question handling, interactive responses); feedback forms (e.g. structured feedback, user ratings)

Follow-up: post-presentation surveys (e.g. audience feedback, evaluation); debriefs (e.g. reflective sessions, feedback synthesis).

Feedback analysis:

Categorisation: thematic coding (e.g. pattern recognition, theme development); sentiment analysis (e.g. positive/negative feedback, sentiment scores)

Implementation: prioritisation (e.g. high-impact feedback, action plans); action points (e.g. specific improvements, task assignments).

Iterative design processes:

Cyclical approaches: Plan-Do-Check-Act (PDCA) (e.g. continuous improvement, iterative cycles)

Agile: sprint planning, iterative development

Prototyping iterations: build-test-revise cycles (e.g. iteration loops, refinement).

Implementation of changes:

Modification tracking: change logs (e.g. record of changes, version history); version control (e.g. document versions, revision tracking)

Continuous improvement: e.g. Kaizen (e.g. incremental improvements, lean principles), lean methodologies (e.g. waste reduction, efficiency improvements).

Documentation of modifications:

Revision history including change records (e.g. documentation of changes, impact assessment); update logs (e.g. chronological updates, modification justification)

Final reports including summary of revisions (e.g. changes overview, final design)

Impact analysis: evaluation of changes, final outcomes.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Conduct small-scale research in relation to a given MedTech project brief</td><td rowspan="2">D1 Evaluate the effectiveness of the chosen research methods and data collection techniques used in conducting the small-scale research of the given MedTech project brief.</td></tr>
<tr><td>P1 Review the user needs and ethical considerations of a given MedTech project brief.

P2 Conduct, using a range of research methods and data collection techniques, a small-scale research project in relation to a given MedTech brief.</td><td>M1 Justify the selection of the research methods and data collection techniques used in conducting the small-scale research of the given MedTech project brief.</td></tr>
<tr><td colspan="2">LO2 Develop a design based on the requirements of a given MedTech project brief</td><td rowspan="5">LO2, LO3 and LO4

D2 Evaluate the original and optimised design for the MedTech project brief, justifying the decisions made in the optimisation of the original design.</td></tr>
<tr><td>P3 Develop a design based on the requirements of a given MedTech project brief.

P4 Review the effectiveness of the design based on the requirements of a given MedTech project brief.</td><td>M2 Justify the design decisions made, including why alternate options were rejected.</td></tr>
<tr><td colspan="2">LO3 Present the design recommendations to an intended audience</td></tr>
<tr><td>P5 Develop an appropriate presentation containing the design recommendations for an intended audience.

P6 Present the recommended design solution for the MedTech brief to an intended audience.</td><td>M3 Analyse the effectiveness of the presentation in communicating the design recommendations to the intended audience.</td></tr>
<tr><td colspan="2">LO4 Refine the design based on stakeholder feedback</td></tr>
<tr><td>P7 Review, with a range of relevant stakeholders, the effectiveness of the design in relation to the identified MedTech brief.

P8 Analyse the results of the stakeholder feedback to identify areas where the design could be refined or improved.</td><td>M4 Refine the design of the given MedTech brief based on the results of the feedback analysis.</td></tr>
</table>

Recommended Resources

Textbooks

Braun, V. and Clarke, V. (2021) *Thematic Analysis: A Practical Guide*. London: Sage Publishing.

Chu, H. (2024) *Research Methods and Design Beyond a Single Discipline: From Principles to Practice*. Abingdon: Routledge.

Daniel, B.K., Harland, T. and Wald, N. (2024) *Higher Education Research Methodology: A Step-by-Step Guide to the Research Process*. Abingdon: Routledge.

Dawson, C. (2016) *100 Activities For Teaching Research Methods*. Los Angeles: Sage Publishing.

Kumar, A. and Praveenakumar, S.G. (2025) *Research Methodology*. Authors Click Publishing.

Langer, A.M. (2008) *System Development Life Cycle (SDLC). Analysis and Design of Information Systems*. 3rd Ed. (pp.10-20). London: Springer.

Newton, R. (2024) *Project Management Step By Step: How to Plan and Manage a Highly Successful Project*. Harlow: Pearson.

Websites

www://adphealth.org/irtoolkit/research-methods-and-data-management/selecting-research-methods.html	ADPHealth Research Methods and Data Management (Toolkit)
www.apm.org.uk	Association for Project Management (General reference)
www.gov.uk/government/publications	Department for Business, Innovation and Skills Guidelines for managing projects – How to organise, plan and control projects (Report)
www://online.hbs.edu/blog/post/data-collection-methods	Harvard Business School 7 Data Collection Methods in Business Analytics (Article)
www.pmi.org.uk	Project Management Institute UK (General reference)

www.teamwork.com/project-management-guide/project-management-methodologies/	Teamwork.com Project Management Methodologies (Article)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 403: Risk Management (ISO 14971)

Unit 406: Regulatory Compliance

Unit 503: Managing a MedTech Project

Unit 504: Data Analytics

Unit 506: Understanding User Needs

Unit 508: Professional Development

Unit 509: ISO Standard Auditing for Medical Devices.

Unit 501: Data Management and Cybersecurity

Unit code: A/651/7107

Unit level: 5

Credit value: 15

Introduction

In the rapidly evolving field of medical technology (MedTech), the management and protection of data are critical to the advancement of patient care and operational efficiency. With the proliferation of sophisticated devices and digital health records, the volume and sensitivity of medical data have increased dramatically, requiring robust data governance procedures and thorough cybersecurity measures. This unit is designed to provide students with a comprehensive understanding of the various types of medical data, the legal and ethical frameworks governing data security, and the strategies required to mitigate cybersecurity threats. This unit is critical for any student pursuing a career in MedTech, providing them with the core knowledge of this highly regulated and technologically complex sector.

The primary aim of this unit is to equip students with the practical knowledge and analytical skills required to handle medical data responsibly, to identify the range of threats against MedTech systems, and to protect these systems against such threats. Through a blend of theoretical learning and practical case study analysis, students will build up to the practical component of the unit, where they will apply cybersecurity theory in the design of a cybersecurity strategy.

In this unit, students will explore several key areas essential to the understanding of data management and cybersecurity in MedTech. Initial topics cover the various types of medical data, ranging from electronic health records (EHRs) to wearable device data, and highlight the importance of data governance. Further exploration into legal and ethical considerations will provide insights into frameworks such as GDPR and HIPAA, highlighting the importance of patient privacy and data security compliance. Subsequently, students will assess the cybersecurity threats associated with MedTech devices, including common threats such as ransomware and unauthorised access. The unit builds to the development of a range of cybersecurity strategies, such as hardware, software, organisational and response strategies, to help effectively mitigate the threat to an identified MedTech device.

On successful completion of this unit, students will possess a detailed understanding of data governance, legal compliance and cybersecurity threat management within the MedTech landscape. These competencies will help students prepare for a variety of roles within the MedTech industry, such as Health Information Manager, Network Security Engineer, MedTech Cybersecurity Analyst and Compliance Officer.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Review the various types of medical data and the importance of data governance in MedTech

LO2 Discuss the legal and ethical considerations for data security and patient privacy

LO3 Assess the cybersecurity threats and vulnerabilities associated with MedTech devices

LO4 Develop a range of strategies to mitigate cybersecurity threats for an identified MedTech scenario.

Essential Content

LO1 Review the various types of medical data and the importance of data governance in MedTech

Types of medical data:

Patient health records: e.g. personal health records (PHRs); electronic health records (EHRs), including structured data, unstructured data, semi-structured data; electronic medical records (EMRs), including diagnoses, medical history, medications, lab results; data interoperability and compatibility

Imaging and diagnostic data: e.g. DICOM format, X-rays, MRIs, ultrasound, CT scans, laboratory results

Wearable and remote monitoring data: e.g. IoT sensors, continuous health tracking, telehealth integration

Genomic and biometric data: e.g. DNA sequencing, fingerprint recognition, AI-driven diagnostics

Administrative and financial data: e.g. billing records, insurance claims, provider reimbursements

Clinical trial and research data: e.g. study protocols, anonymised datasets, real-world evidence (RWE).

The five pillars of data governance in MedTech:

Quality: e.g. accuracy, consistency, completeness, timeliness, reliability; protocols to ensure integrity and reliability, e.g. validation techniques, redundancy checks, error handling (detection, correction)

Stewardship: e.g. manufacturer, healthcare provider, third-party vendor roles, Information Commissioner's Office (ICO), Data Controller

Protection: e.g. security measures, data access controls, encryption, policies

Life cycle management: e.g. collection, storage, organisation, usage (e.g. access, sharing, updating, deletion), archiving

Importance: e.g. improved data quality and reliability, better decision-making, faster product development, improved business insights (e.g. customer behaviour, market trends, operational efficiency); identification of data inconsistencies (e.g. errors, redundancies); improved regulatory compliance and risk management, improved safety.

LO2 **Discuss the legal and ethical considerations for data security and patient privacy**

Legal frameworks and compliance standards:

General Data Protection Regulation (GDPR): data processing principles, right to be forgotten, data minimisation

Health Insurance Portability and Accountability Act (HIPAA): PHI protection, security rule, breach notification

Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR): compliance reporting (e.g. data breach reporting requirements, incident disclosure); post-market surveillance

ISO 27001 and ISO 27799: information security management, risk-based approach, audit readiness

FDA Cybersecurity Guidance for Medical Devices: NIST Cybersecurity Framework 2.0, secure software development, threat mitigation

Other legislation: European Data Governance Act 2022 (DGA), 21st Century Cures Act 2016

NHS Data Security Standards (UK): Cyber Essentials, digital health records compliance

Audits: internal audits, external audits, compliance checks.

Ethical considerations:

Principles: autonomy, beneficence, non-maleficence, justice

Best practices: privacy by design, data minimisation, secure communication

Patient consent and data transparency: informed consent, opt-in/opt-out models

Bias in AI and automated decision-making: ethical AI, fairness in algorithms, explainability in AI models

Data breaches and incident disclosure: ethics of breach reporting, corporate responsibility

Digital inclusion and accessibility: healthcare disparities, ensuring fair access to digital health solutions

Patient privacy: e.g. principles including consent, confidentiality, data-sharing agreements; mechanisms, e.g. anonymisation, pseudonymisation, secure storage, multi-factor authentication (MFA).

LO3 **Assess the cybersecurity threats and vulnerabilities associated with MedTech devices**

Cybersecurity threats in MedTech:

Ransomware and malware attacks: e.g. data encryption, extortion risks, ransomware-as-a-service (RaaS), zero-day attacks

Unauthorised access and insider threats: e.g. privilege escalation, phishing attacks, credential leaks

Man-in-the-middle (MITM) Attacks: e.g. data interception, compromised real-time monitoring

Denial-of-Service (DoS) attacks: e.g. system outages, emergency response disruption, resilience strategies

Supply chain vulnerabilities: e.g. weak third-party software, vendor cybersecurity gaps

Cloud security risks: e.g. API vulnerabilities, shared responsibility models, cloud misconfiguration

Impact: e.g. patient safety, data loss, financial loss, reputational damage.

System vulnerabilities:

Software: e.g. outdated software, unpatched vulnerabilities (e.g. OS security updates, application updates, system patches, out-of-date virus database), outdated protocols

Hardware: e.g. outdated hardware, physical access, device tampering, lack of firmware updates; outdated software architecture (e.g. flat files versus relational databases, database access controls)

Network: e.g. insecure connections, poor password policies (e.g. weak passwords, password sharing, lack of password change), external devices (e.g. USB devices, mobile devices, BYOD); lack of regular virus scans

Human factors: e.g. user errors, lack of awareness, lack of knowledge, poor training

Organisational factors: e.g. lack of effective policies (e.g. email use, internet use, social media use, BYOD, account use, acceptable use); poor training (e.g. lack of budget, organisational culture), morale.

Risk assessment strategies:

Threat modelling and risk Assessment: e.g. identifying attack vectors, evaluating security postures, risk analysis, threat modelling, vulnerability assessments

Tools: e.g. penetration testing, security audits, risk management software

Risk assessment: e.g. probability, severity, risk matrix, security prioritisation, critical assets identification, impact assessment, recovery (e.g. data, operational readiness); downtime, costs, reputation, safety.

LO4 Develop a range of strategies to mitigate cybersecurity threats for an identified MedTech scenario

Security by design concepts in medical devices:

Secure firmware and software updates: e.g. patch management, automatic security updates, rollback mechanisms

Device encryption and secure boot mechanisms: e.g. cryptographic security, trusted execution environments

End-to-end data protection: data-in-transit security, e.g. TLS/SSL encryption, secure messaging protocols

User authentication and access controls: e.g. biometric security, multi-factor authentication (MFA)

Cloud and edge computing security: e.g. hybrid cloud risks, data federation, edge security protocols.

Software security strategy concepts:

Secure software development life cycle (SDLC): e.g. secure coding best practices, penetration testing

Secure communication protocols: WPA3 for IoT medical devices, TLS 1.3 for encrypted connections

Data protection: methods, e.g. encryption, secure data transmission, data redundancy; tools, e.g. encryption software, secure communication platforms; database access controls, relational versus NoSQL databases.

Network security strategy concepts:

Zero-trust security models: e.g. least privilege access, role-based authentication

Network security and encryption techniques: e.g. firewalls, intrusion prevention, intrusion detection systems (IDS), antivirus software, VPN encryption, network monitoring software, secure access management.

Organisational security strategy concepts:

User training: programmes (e.g. phishing awareness, secure password practices, incident reporting); methods (e.g. regular training sessions, simulation exercises, security drills, role-specific training)

Compliance and regulatory documentation: e.g. audit logs, cybersecurity policies (e.g. email use, internet use, BYOD, acceptable use, account use, network use, data protection), risk mitigation documentation

Continuous cybersecurity monitoring and auditing: e.g. SIEM tools, behavioural anomaly detection; monitoring strategies, including security logs, threat intelligence, performance metrics

Auditing: regular audits, compliance checks, vulnerability scans

Updating: security policy revisions, technology upgrades.

Response strategy concepts:

Incident response and breach recovery: e.g. forensic analysis, rollback procedures, response protocols

Organisational response: e.g. improved security policies, employee training, incident response plans

Incident response: phases including detection, containment, eradication, recovery; lessons learned, including post-incident reviews, continuous improvement

Implementation: including security controls, best practices, compliance routines.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Review the various types of medical data and the importance of data governance in MedTech</td><td rowspan="5">LO1 and LO2

D1 Critically evaluate, using a range of real-world case studies, the effectiveness of data governance on the legal and ethical considerations for the security and privacy of patient data within the MedTech sector.</td></tr>
<tr><td>P1 Examine, using a range of real-world case studies, the different types of medical data used in the MedTech sector.

P2 Review, using a range of real-world case studies, the four pillars of data governance covering the use of medical data in the MedTech industry.</td><td>M1 Analyse, using a range of real-world case studies, the various types of medical data and the importance of data governance within the MedTech sector.</td></tr>
<tr><td colspan="2">LO2 Discuss the legal and ethical considerations for data security and patient privacy</td></tr>
<tr><td>P3 Examine, using a range of real-world case studies, the various legal frameworks and compliance standards governing the use of medical data in the MedTech sector.

P4 Examine, using a range of real-world case studies, the ethical considerations concerning the use of medical data in the MedTech sector.</td><td>M2 Analyse, using a range of real-world case studies, the legal and ethical considerations for data security and patient privacy within the MedTech sector.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Assess the cybersecurity risks and vulnerabilities associated with MedTech devices		**LO3 and LO4** **D2** Justify the choices made in the development of the cybersecurity strategy for the identified MedTech scenario, showing how the selected threat mitigation strategies help minimise the identified cybersecurity risks and vulnerabilities.
P5 Assess, using a range of real-world scenarios, a range of cybersecurity risks and vulnerabilities associated with devices in the MedTech sector. **P6** Review, using a range of real-world scenarios, a range of risk assessment strategies that can be used for devices in the MedTech sector.	**M3** Evaluate, using a range of real-world scenarios, the cybersecurity risks and vulnerabilities associated with MedTech devices and the strategies for risk assessment.	
LO4 Develop a range of strategies to mitigate cybersecurity threats for an identified MedTech scenario		
P7 Review, using real-world examples as illustration, a range of strategies to mitigate cybersecurity threats against MedTech devices. **P8** Devise a cybersecurity strategy to mitigate a range of identified cybersecurity threats that could potentially threaten the identified MedTech scenario.	**M4** Evaluate the effectiveness of the devised cybersecurity strategy in protecting the identified MedTech scenario from a range of identified cybersecurity threats.	

Recommended Resources

Textbooks

Agrawal, R., Rathore, P.S., Deverajan, G.G. and Divivedi, R.R. eds. (2025) *Artificial Intelligence and Cybersecurity in Healthcare*. Hoboken: John Wiley & Sons.

Cohen, I.G., Minssen, T., Price II, W.N., Robertson, C. and Shachar, C. eds. (2022) *The Future of Medical Device Regulation: Innovation and Protection*. Cambridge: Cambridge University Press.

Li, K.C., Chen, X. and Susilo, W. eds. (2019) *Advances in Cyber Security: Principles, Techniques, and Applications*. New York: Springer.

Ray, A. (2021) *Cybersecurity for Connected Medical Devices*. London: Academic Press.

Thakur, K. and Pathan, A.S.K. (2020) *Cybersecurity Fundamentals: A Real-World Perspective.* Boca Raton: CRC Press.

Wirth, A., Gates, C. and Smith, J. (2024) *Medical device cybersecurity for engineers and manufacturers*. 2nd Ed. Boston: Artech House.

Websites

www.cisa.gov/resources-tools/resources/insider-threat-mitigation-guide	Insider Threat Mitigation Guide (Article)
www.cisa.gov/topics/cyber-threats-and-advisories	Cyber Threats and Advisories (Resource)
www://digital.nhs.uk/cyber-and-data-security/guidance-and-assurance/guidance-for-procuring-and-deploying-connected-medical-devices	Cybersecurity guidance for procuring and deploying Connected Medical Devices (CMDs) (Resource)
www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity	Cybersecurity (Resource)
www.greenlight.guru/blog/cybersecurity-medical-device	Cybersecurity for Medical Devices: Best Practices from Regulatory Standards (Article)
www.imdrf.org/working-groups/medical-device-cybersecurity-guide	Medical Device Cybersecurity Guide (Resource)
www.ncsc.gov.uk/collection/risk-management	Risk management (Resource)

www.ncsc.gov.uk/guidance/mitigating-malware-and-ransomware-attacks	Mitigating malware and ransomware attacks (Guidance)
www.nist.gov/cyberframework	National Institute of Standards and Technology (Resource)
www.security.gov.uk/policy-and-guidance/secure-by-design/activities/performing-a-security-risk-assessment/	Who is involved How to perform a cybersecurity risk assessment Performing a security risk assessment (Article)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 404: Applied Programming

Unit 406: Regulatory Compliance

Unit 407: Software and UI/UX Design

Unit 511: Hardware, Robotics and Autonomous Systems in MedTech

Unit 514: Emerging Trends and Technologies.

Unit 502: Computer Systems Validation

Unit code: **D/651/7108**

Unit level: **5**

Credit value: **15**

Introduction

Computer Systems Validation (CSV) represents a critical component of the MedTech industry, as it ensures that computer systems and software operate reliably and meet regulatory standards. In a landscape where technology and patient care meet, CSV plays an essential role in maintaining data integrity, system functionality and compliance with strict regulatory requirements. As the MedTech landscape continues to evolve, having robust CSV protocols becomes even more important, allowing for safer and more efficient patient care.

This unit is designed to provide students with a comprehensive understanding of CSV within the MedTech context, equipping them with the knowledge to navigate and implement effective validation processes.

The primary aim of this unit is to help students understand the foundational principles and regulatory frameworks underpinning Computer Systems Validation in MedTech. The unit content is designed to offer practical insights into risk management, roles and responsibilities, and the due diligence required to maintain compliant and efficient systems.

This unit encompasses a wide range of topics vital for the understanding and execution of Computer Systems Validation in MedTech. Key areas of focus include the regulatory requirements (such as FDA 21 CFR Part 11 and EU Annex 11), risk management strategies, and the detailed development and validation life cycle processes. Students will also explore supplementary considerations, such as security management and disaster recovery, which are critical for maintaining the validated state of computer systems. Students will apply the unit theory in the development of a CSV audit strategy for an identified MedTech scenario, preparing them for real-world challenges in ensuring system validation and compliance in the MedTech sector.

On successful completion of this unit, students will have developed a robust set of skills essential for navigating the complexities of CSV in the MedTech industry. These skills are directly linked to a variety of key roles in quality assurance, regulatory affairs and IT management within the MedTech sector.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Review the key principles and regulatory requirements of CSV in MedTech

LO2 Explain the development and validation life cycle process in MedTech

LO3 Explore the range of additional considerations when performing CSV in MedTech

LO4 Develop a CSV audit strategy for an identified MedTech scenario.

Essential Content

LO1 **Review the key principles and regulatory requirements of CSV in MedTech**

Introduction to CSV concepts:

Definition: e.g. compliance assessment, functionality confirmation, integrity assurance, reliability evaluation, validation protocol, hardware verification, software validation

Purpose: e.g. risk mitigation, quality assurance, regulatory compliance, system reliability

Importance: e.g. regulatory requirement, patient safety, error reduction, maintenance system reliability, quality improvement.

Key principles – managing risk:

Risk management: risk identification, risk analysis, risk control

Risk assessment: risk scenarios, risk probability, risk impact, hazard analysis

Risk mitigation: preventive controls, corrective actions, risk communication

Risk acceptance: risk decision criteria, risk tolerance, residual risk.

Key principles – roles:

Validation team: e.g. team composition, roles and responsibilities, qualifications, project involvement, communication protocols, cross-functional collaboration

Quality assurance: e.g. quality control measures, compliance monitoring, internal audits, process audits, system audits, quality system management, continuous improvement

Regulatory affairs: e.g. compliance strategy, regulatory submissions, interaction with authorities, regulatory updates, documentation review, risk-based approaches

Information technology: e.g. system configuration, software implementation, IT security protocols, data management, hardware requirements, system maintenance.

Key principles – due diligence:

System/software categories: e.g. from vendors, from sponsors, built in-house

Validation requirements: e.g. user requirements, specifications, system functionalities, system testing, fitness for purpose

CSV audit: e.g. audit, validation certificate, approval

Vendor-supplied systems: e.g. validation evidence, validation certificates, supporting documentation, R&D office consultation, audit

Sponsor-supplied systems: end product, user requirement specifications (URS), functionality documentation

In-house systems: e.g. full validation process, compliance, performance

Due diligence procedures: e.g. sequential date checks, complete testing, agree and sign off specifications and test scripts, validation report, address concerns, mitigate risks, formal risk assessment, document findings, complete and evidence mitigation actions

Contractual obligations: e.g. understanding legal agreements, ensuring clear definition of responsibilities, maintaining compliance with regulatory requirements.

CSV regulatory requirements:

FDA 21 CFR Part 11: e.g. electronic records, electronic signatures, audit trails, system validation

EU Annex 11: e.g. computerised systems, access control, data integrity, validation documentation

GxP Regulations: e.g. Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Automated Manufacturing Practice (GAMP)

ISO 13485: medical device quality system, regulatory requirements, documentation control.

LO2 **Explain the development and validation life cycle process in MedTech**

Development process concepts:

Project initiation: e.g. project scope, project goals, stakeholder identification, resource allocation, timeline

Requirements gathering: e.g. user requirements specification (URS), system functionality, stakeholder engagement, requirement validation

System design: e.g. system architecture, user interface design, data model, software specification

Implementation: e.g. coding, UI/UIX development, configuration, system setup, integration, version control

Integration and testing: e.g. unit testing, integration testing, functional and non-functional testing, regression testing, system testing, UAT (User Acceptance Testing), alpha testing, beta testing

Team integration: e.g. test teams, software development teams, making effective contributions

Maintenance: e.g. modifications (e.g. system, component); change requests (e.g. customer, defect log), ongoing support including software, hardware (e.g. software patch, firmware upgrade, regular vulnerability sweeps, penetration testing).

Validation process concepts:

Validation planning: e.g. validation plan document, validation strategy, validation team roles, timeline

Installation Qualification (IQ): e.g. physical installation, environment setup, hardware-software compatibility, maintenance (e.g. validated state, data integrity), contingency measures (e.g. regular backups, updates), preventive measures (e.g. logical and physical security, account access, firewalls, anti-virus)

Operational Qualification (OQ): e.g. functional and non-functional testing, performance consistency, boundary testing, error handling, unit testing, integration testing, iterative testing; installation issues

Performance Qualification (PQ): e.g. performance demonstration, operational conditions, system limits, user acceptance testing (UAT).

Revalidation concepts:

Periodic Review: e.g. scheduled assessments, system performance checks, compliance verification, documentation review

System updates: e.g. software patches, hardware upgrades, system enhancements, version management

Continuous improvement: e.g. feedback incorporation, process optimisation,

Change control concepts:

Change request: e.g. change initiation, change description, change justification, change categorisation

Change impact assessment: e.g. risk analysis, validation scope, impact on system function, stakeholder consultation

Change documentation: e.g. change control form, supporting documents, approval records, communication logs

Change approval: e.g. change review, approval process, implementation plan, timeline.

LO3 **Explore the range of additional considerations when performing CSV in MedTech**

Additional considerations:

Security management: e.g. access control, security levels, password access limits, current user list, access removal, data encryption, audit trails, intrusion detection systems, cybersecurity measures, physical security measures

Disaster recovery: e.g. disaster recovery plan, failover systems, data recovery procedures, recovery time objective (RTO), recovery point objective (RPO)

Backup and restore: e.g. backup schedule, backup media, data verification, backup locations, restore testing

Deviation management: e.g. deviation reporting, deviation investigation and assessment, root cause analysis, corrective and preventive actions (CAPA), user awareness, documentation

Documentation management: e.g. document control, version control, audit trails, archiving, security, chain of responsibility.

Fundamentals of legacy systems:

System assessments: e.g. system inventory, risk analysis, compliance evaluation, functionality review

Migration planning: e.g. data migration strategy, testing plan, timeline, risk mitigation, system validation

Legacy system risk: e.g. data integrity risk, security vulnerabilities, support and maintenance challenges, outdated technology

Retrospective validation: e.g. document recovery, adequacy of documents, degree of customisation, future intentions.

Decommissioning concepts:

Decommissioning planning: e.g. decommissioning strategy, data archival, stakeholder communication, timeline

Data archival: e.g. data retention requirements, storage media, security, compliance with regulatory requirements

System retirement: e.g. system shutdown procedure, equipment disposal, user communication, documentation.

LO4 **Develop a CSV audit strategy for an identified MedTech scenario**

Audit planning:

Audit scope: e.g. objectives, systems to be audited, audit boundaries, organisational alignment

Audit objectives: e.g. compliance verification, system functionality, data integrity, process improvement

Audit criteria: e.g. regulatory requirements, internal policies, industry standards

Audit team selection: e.g. skill set requirements, team composition, roles and responsibilities; collaboration techniques (e.g. audit team, stakeholders); conflict management (e.g. identification, mitigation, resolution, negotiation).

Audit preparation:

Checklists: e.g. audit checklist creation, compliance criteria, operational criteria, technical criteria

Documentation review: e.g. current documentation assessment, compliance documentation, historical performance records

Audit schedule: e.g. timeline, milestones, coordination with stakeholders, resource allocation

Communication plan: e.g. stakeholder notification, communication channels, periodic updates, feedback mechanism.

Audit execution:

Opening meeting: objectives overview, audit agenda, responsibilities, ground rules.

Data collection and analysis: e.g. data sources, data collection methods, data analysis tools, validation of findings

Interviews and observation: e.g. interview protocols, observational methods, data recording, non-conformance identification

Non-conformance reporting: e.g. issue recognition, evidence gathering, documentation, impact assessment.

Audit reporting:

Summary of findings: compliance status, deficiencies, strengths, areas for improvement

Non-conformance categorisation: by severity, by impact, by type, corrective actions required

Corrective action plan: action items, responsible parties, timelines, follow-up

Management review: report submission, findings discussion, approval, implementation tracking.

Learning Outcomes and Assessment Criteria

Pass	Merit	Distinction
LO1 Review the key principles and regulatory requirements of CSV in MedTech		**LO1, LO2 and LO3** **D1** Critically evaluate, using a range of real-world case studies, the effectiveness of computer systems validation within the MedTech sector in the context of the regulatory requirements.
P1 Examine, using a range of real-world case studies, the key principles of computer systems validation used in the MedTech sector. **P2** Review, using a range of real-world case studies, the CSV regulatory requirements of the MedTech sector.	**M1** Analyse, using a range of real-world case studies, the key principles and regulatory requirements of CSV in MedTech.	
LO2 Explain the development and validation life cycle process in MedTech		
P3 Explain, using a range of real-world case studies, the development and validation life cycle process used within the MedTech sector. **P4** Examine, using a range of real-world case studies, how revalidation and change control are used as part of the development and validation life cycle process within the MedTech sector.	**M2** Analyse, using a range of real-world case studies, the development and validation life cycle process used within the MedTech sector.	
LO3 Explore the range of additional considerations when performing CSV in MedTech		
P5 Explore, using a range of real-world scenarios, the additional considerations when performing CSV in MedTech. **P6** Review, using a range of real-world scenarios, the consideration of legacy systems and decommissioning when performing CSV in MedTech.	**M3** Evaluate, using a range of real-world scenarios, the range of additional considerations when performing CSV in MedTech.	

Pass	Merit	Distinction
LO4 Develop a CSV audit strategy for an identified MedTech scenario		
P7 Develop a CSV audit strategy for a defined MedTech scenario, considering planning, preparation, execution and reporting. **P8** Review the developed audit strategy with a variety of key stakeholders to identify a range of strengths, weaknesses and areas for improvement.	**M4** Justify, using the contents of the stakeholder review, the choices made in the development of the audit strategy for an identified MedTech scenario.	**D2** Critically evaluate the effectiveness of the audit strategy in how well it aligns with the identified objectives of the MedTech scenario, making recommendations for any future actions.

Recommended Resources

Textbooks

Huber, L. (2023) *Validation of Computerized Analytical Systems*. Boca Raton: CRC Press.

López, O. (2018) *Pharmaceutical and Medical Devices Manufacturing Computer Systems Validation*. Boca Raton: CRC Press.

Stein, R.T. (2006) *The Computer System Risk Management and Validation Life Cycle*. Spring: Paton Professional.

Wingate, G. ed. (2000) *Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers.* 1st Ed. Boca Raton: CRC Press.

Wingate, G. ed. (2024) *Computer Systems Validation: Quality Assurance, Risk Management, and Regulatory Compliance for Pharmaceutical and Healthcare Companies*. 1st Ed. Boca Raton: CRC Press.

Websites

www.getreskilled.com/what-is-computer-systems-validation-csv/	What is meant by Computer System Validation (CSV)? (Article)
www.greenlight.guru/blog/csa-vs-csv	CSV vs. CSA: Exploring FDA's New Software Validation Approach (Blog)
www.greenlight.guru/blog/design-verification-and-design-validation	What's the difference between design verification and design validation? (Blog)
www://mhrainspectorate.blog.gov.uk/2017/04/20/computer-system-validation-gcp/	Computer System Validation – GCP (Blog)
www://pmc.ncbi.nlm.nih.gov/articles/PMC11416705/	The Essential Guide to Computer System Validation in the Pharmaceutical Industry (Resource)
www.qbdgroup.com/en/a-complete-guide-to-computer-system-validation	A Complete Guide to Computer System Validation (CSV) (Resource)
www.qbdgroup.com/en/blog/change-control-management	Change Control Management: how to keep your systems compliant? (Blog)

www.qbdgroup.com/en/blog/what-is-decommissioning-in-csv	What is decommissioning in CSV? (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 406: Regulatory Compliance

Unit 408: Designing a MedTech Project

Unit 506: Understanding User Needs

Unit 509: ISO Standard Auditing for Medical Devices

Unit 513: Quality by Design.

Unit 503: Managing a MedTech Project (Pearson Set)

Unit code: **F/651/7109**

Unit level: **5**

Credit value: **15**

Introduction

This unit is a ***Pearson-set unit***. The project brief will be set by the centre, based on a theme provided by Pearson (this will change annually). The theme and chosen project within the theme will enable students to explore and examine a relevant and current topical aspect of MedTech in the context of a professional environment.

The skills of project management are highly sought after by employers in all areas of MedTech, as the ability to plan, procure and execute a MedTech project efficiently requires a range of specific skills in leadership, time management, problem solving, budgeting and communication.

The aim of this unit is to offer students an opportunity to demonstrate the skills required for managing and implementing a ***small-scale MedTech project***. They will review the different project management methodologies as well as the different phases of the project life cycle. They will undertake independent research and investigation to design and implement a project management plan for a MedTech project that meets appropriate business aims and objectives. Students will reflect on the effectiveness of their planned project against the set of starting objectives to help identify any areas of improvement. Such reflective skills are an essential part of any continuing professional development (CPD).

On successful completion of this unit, students will have the confidence to engage in decision-making, problem solving and research activities using project-management skills. They will have the fundamental knowledge and skills to enable them to investigate and examine relevant MedTech concepts in a work-related context, determine appropriate outcomes, decisions or solutions, and present evidence to various stakeholders in an acceptable and understandable format. These skills are directly linked to roles such as Project Manager, Data Analyst and Project Designer.

***Please refer to the accompanying *Pearson-set Assignment Guide and Theme and Topic Release* document on HN Global for further support and guidance on the delivery of the Pearson-set unit.**

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explore the key elements of project life cycle management within the MedTech sector

LO2 Devise a project management plan for a MedTech project to meet a set of defined objectives

LO3 Implement a project management plan for a MedTech project to meet a set of defined objectives

LO4 Review the effectiveness of a planned MedTech project against a set of starting objectives.

Essential Content

LO1 Explore the key elements of project life cycle management within the MedTech sector

Project management methodologies:

Methodologies, frameworks: e.g. waterfall, agile, hybrid, critical path, critical chain, Scrum, Kanban; earned value management (EVM), e.g. planned value, earned value, actual cost

Team organisational structures: e.g. functional, project, matrix, benefits, differences

Project life cycle approaches: e.g. linear, iterative, hybrid, benefits, differences

Project structures: project (e.g. deliverables, objectives, outputs); programme (e.g. outcomes, higher complexity, longer timescale, higher budget, higher risk); portfolio (e.g. strategic grouping, return on investment (ROI), mix of projects and programmes, higher risk, no defined endpoint).

Phases of the project life cycle:

Initiation phase: e.g. project objectives, feasibility studies, initial project scope, stakeholder identification, project charter creation, projects versus business as usual, organisational alignment

Planning phase: e.g. detailed project plan, work breakdown structure (WBS), milestones, timelines, resource planning, Gantt charts, scheduling, budget planning, risk planning, communication planning; estimation methods (e.g. top-down, bottom-up, analogous, three-point, parametric)

Execution phase: e.g. task allocation, project team roles, responsibilities, resource utilisation, project monitoring, progress tracking, task management, project management software, time tracking

Monitoring and control phase: e.g. configuration management, performance metrics, key performance indicators (KPIs), process audits, corrective actions, quality control, variance analysis, change control, project reporting

Closure phase: e.g. project handover, deliverables acceptance, post-project evaluation, lessons learned, final project report, project documentation, archiving, project closeout meeting.

Project management constructs:

Advantages of project management: e.g. importance, efficiency, regulatory compliance, time management, budget adherence, quality assurance, achieving outcomes

Roles in project management: e.g. Assistant Project Manager, Junior Project Manager, Project Team Leader – responsibilities, outcome achievement

Project management skills: e.g. planning, organising, leadership, communication, budget management, spending decisions, flexibility; collaboration techniques (e.g. project team, stakeholders); conflict management (e.g. identification, mitigation, resolution, negotiation)

Leadership styles: e.g. flexible, agile, adaptable – team motivation, performance impact, work delegation, negotiation skills, meeting management.

Regulatory and compliance requirements:

Regulatory bodies: e.g. FDA (Food and Drug Administration), EMA (European Medicines Agency), MHRA (Medicines and Healthcare products Regulatory Agency), TGA (Therapeutic Goods Administration)

Compliance standards: e.g. ISO 13485 (Medical devices – Quality management systems), ISO 14971 (Medical devices – risk management), IEC 62304 (medical device software – software life cycle processes), CE marking, MDR (Medical Device Regulation), IVDR (In Vitro Diagnostic Regulation)

Documentation: e.g. regulatory submissions, pre-market approval (PMA), 510(k) submissions, design history file (DHF), device master record (DMR), technical file, labelling requirements, user manuals, clinical evaluation report (CER)

Clinical trials: e.g. phases of clinical trials, ethical approvals, informed consent, institutional review boards (IRBs), Good Clinical Practice (GCP), clinical investigation plans (CIP)

Post-market surveillance: e.g. vigilance reporting, medical device reporting (MDR), post-market clinical follow-up (PMCF), regulatory updates, compliance auditing.

LO2 **Devise a project management plan for a MedTech project to meet a set of defined objectives**

Project risk management plan:

Risk identification: hazard analysis, risk matrix

Risk assessment: probability, impact, risk prioritisation

Risk control: mitigation strategies, risk monitoring

Contingency planning: fallback plans, risk communication.

Quality management plan:

Quality planning: quality objectives, quality standards

Quality assurance: process validation, compliance audits

Quality control: inspection, testing, quality metrics

Continuous improvement: quality feedback, process refinement.

Project management plan:

Objectives: e.g. defining, scoping, purpose, deliverables, timescales, cost, quality, change management, risk management, stakeholder communication; purpose format, significance

Business case: e.g. definition, maintenance, integrated management, benefits on successful delivery

Tools: e.g. Microsoft Project, Asana, Trello, Smartsheet, Excel, activity plans, work breakdown structure (WBS), Gantt charts

Progress measurement: e.g. staff hours, earned value (EV), progress tracking, s-curves, critical path analysis, reporting, milestone trending, KPIs

Problem solving: brainstorming, cause-and-effect diagrams, fishbone diagrams, force field analysis

Research methods: e.g. primary, secondary, qualitative, quantitative – questionnaires, interviews, observation, sample population selection, data collection

Sampling: e.g. probability, non-probability – monitoring tools, Gantt charts

Components: e.g. scope statement, work breakdown structure (WBS), schedule, budget, risk register, communication plan

Stakeholder management: identification, analysis, engagement, perspectives, interests.

Ethical considerations:

Transparency: e.g. information sharing, open communication, stakeholder engagement, clarity in decision-making

Integrity: e.g. honesty, accountability, trustworthiness, fairness

Responsibility: e.g. duty of care, risk management, resource stewardship, impact assessment

Compliance: e.g. legal adherence, regulatory standards, policy alignment, corporate governance

Diversity: e.g. cultural awareness, gender equality, inclusive opportunities, multigenerational participation

Accessibility: e.g. equal access, barrier-free environment, assistive technologies, universal design

Collaboration: e.g. team cohesion, cross-functional groups, inclusive feedback, mutual respect

Equity: e.g. fair treatment, equitable resource distribution, tailored support, bias elimination.

LO3 **Implement a project management plan for a MedTech project to meet a set of defined objectives**

Pre-implementation phase:

Pre-project preparation: resource allocation, team onboarding, kick-off meetings, project roadmaps, tools setup.

Implementation phase:

Project execution: e.g. task management, resource management, time management, project schedule adherence

Project monitoring: e.g. reporting techniques, performance tracking, interpretation, stakeholder reporting.

Issue resolution: e.g. problem-solving techniques, decision-making models, conflict resolution, escalation processes, corrective actions

Data analysis: e.g. coding, charts, graphs, trend analysis, pictograms, pie charts, bar charts, frequency curves, histograms, line graphs, scattergrams

Forecasting: scatter (XY) graphs, linear trend lines – reliability assessment.

Communication: e.g. stakeholder updates, project meetings, communication channels, status reports, meeting minutes, information dissemination

Behaviours: e.g. flexibility, adaptability, accountability, task ownership, acting professionally (e.g. integrity, honesty, confidentiality).

Post-implementation phase:

Analysis and evaluation: e.g. digital techniques, tools – SurveyMonkey, Google Forms, Zoho Survey, spreadsheets

Data presentation: e.g. tables, simplification, understanding data – validity, objectivity, evidence-based results.

Communicating results:

Methods: written, verbal; mediums – reports, online, presentations

Multimedia tools: e.g. PowerPoint, Prezi, Google Slides, Microsoft Sway, Adobe Spark

Video conferencing: e.g. Zoom, Teams, Adobe Connect, GMeet, Slack

Communication skills: verbal, non-verbal – eye contact, pitch, pace, persuasion, negotiation, stakeholder influencing

Presenter conduct: presentation, behaviour, attire, attitude, professionalism, preparation, organisation

Convincing arguments: logical findings, evaluative conclusions – project outcomes presentation

EDI considerations: e.g. audience suitability, socioeconomic background, linguistic variety, tech capability, presentation adaptability, subject relevance, appropriate imagery.

LO4 **Review the effectiveness of a planned MedTech project against a set of starting objectives**

Stakeholders and feedback:

Feedback collection: stakeholder feedback, customer feedback, team evaluations, feedback surveys, focus groups

Stakeholder management: identification, analysis, engagement, perspectives, interests.

MedTech project review:

Reflection versus evaluation: e.g. performance reflection, project evaluation – research process, information gathering, data collection, argument quality, evidence use

Performance evaluation: e.g. key performance indicators (KPIs), project success criteria, project metrics, performance dashboards

Project review: e.g. value assessment, achievements, limitations, future improvements

Techniques: e.g. identifying and monitoring risks, managing issues, planning and implementing responses

Project context understanding: e.g. PESTLE, SWOT, VUCA – external factors, internal analysis, dynamic environments

Project success factors: e.g. efficiency, effectiveness, goals, quality, compliance, best practices, continuous improvement.

Post-review actions:

Lessons learned, post-project review, improvement recommendations, lessons learned database, project retrospective, root cause analysis

Reflection cycle: e.g. future behaviour, feedback response, adaptability, generating new ideas

Reflective writing: e.g. personal development, critical, objective reflection, research journey

Project documentation: e.g. final report, project archiving, data retention policies, project history logs, documentation standards.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explore the key elements of project life cycle management within the MedTech sector</td><td rowspan="2">D1 Critically evaluate the key elements of project life cycle management within the MedTech sector.</td></tr>
<tr><td>P1 Explore the key project life cycle methodologies, phases and constructs that can be used for project management within the MedTech sector.

P2 Discuss, using a range of real-world examples, the regulatory and compliance requirements of project life cycle management within the MedTech sector.</td><td>M1 Assess the key elements of project life cycle management within the MedTech sector.</td></tr>
<tr><td colspan="2">LO2 Devise a project management plan for a MedTech project to meet a set of defined objectives</td><td rowspan="4">LO2 and LO3

D2 Critically evaluate the project management plan and its implementation in the effectiveness of meeting the defined objectives for a MedTech project.</td></tr>
<tr><td>P3 Develop the key risk and quality control management plans for the identified MedTech project.

P4 Devise a project management plan for a MedTech project to meet a set of defined objectives.</td><td>M2 Justify the identified project management, risk management and quality management plan for a MedTech project to meet a set of defined objectives.</td></tr>
<tr><td colspan="2">LO3 Implement a project management plan for a MedTech project to meet a set of defined objectives</td></tr>
<tr><td>P5 Implement a project management plan for a MedTech project to meet a set of defined objectives.</td><td>M3 Assess the implementation of the project management plan for a MedTech project to meet a set of defined objectives.</td></tr>
<tr><td colspan="2">LO4 Review the effectiveness of a planned MedTech project against a set of starting objectives</td><td rowspan="2">D3 Justify the refinements to the project plan based on the results of the feedback analysis.</td></tr>
<tr><td>P6 Review, with a range of relevant stakeholders, the effectiveness of the planned MedTech project against a set of starting objectives.

P7 Analyse the results of the stakeholder feedback to identify areas where the project plan could be refined or improved.</td><td>M4 Refine the project plan based on the results of the feedback analysis.</td></tr>
</table>

Recommended Resources

Textbooks

Burke, R. (2013) *Project Management: Planning and Control Techniques*. 5th Ed. Chichester: John Wiley & Sons.

Crawford, J.K. (2021) *Project Management Maturity Model*. 4th Ed. Baco Raton: CRC Press.

Donzé, P.Y. (2022) *Medtech*. Singapore: Springer Singapore.

Elahi, B. (2021) *Safety Risk Management for Medical Devices*. 2nd Ed. London: Academic Press.

Geisler, E. and Heller, O. (2012) *Management of Medical Technology: Theory, Practice and Cases.* Vol. 2. Berlin: Springer Science & Business Media.

Jeynes, J. (2023) *Risk Management: 10 Principles*. 2nd Ed. Baco Raton: CRC Press.

Juuso, I. (2022) *Developing an ISO 13485-Certified Quality Management System: An Implementation Guide for the Medical-Device Industry*. Baco Raton: CRC Press.

Kerzner, H. (2025) *Project Management: A Systems Approach to Planning, Scheduling, and Controlling*. 14th Ed. Hoboken: John Wiley & Son.

Newton, R. (2024) *Project Management Step By Step: How to Plan and Manage a Highly Successful Project*. Harlow: Pearson.

Websites

www.apm.org.uk	Association for Project Management (General reference)
www.gov.uk/government/publications	Department for Business, Innovation and Skills Guidelines for managing projects – How to organise, plan and control projects (Report)
www.greenlight.guru/blog/iso-14971-risk-management	Risk Management for Medical Devices: The Definitive Guide (Blog)
www.greenlight.guru/blog/project-management-in-medtech	Project Management in MedTech (Podcast)
www.pmi.org.uk	Project Management Institute UK (General reference)

www.universitylabpartners.org/blog/quality-assurance-and-quality-control-for-biotech-and-medtech-startups	Quality Assurance and Quality Control for Biotech and Medtech Startups (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 406: Regulatory Compliance.

Unit 504: Data Analytics

Unit code: **K/651/7110**

Unit level: **5**

Credit value: **15**

Introduction

Data analytics is revolutionising the MedTech sector by enhancing innovation, efficiency and patient outcomes. Predictive analytics helps in forecasting device failures and scheduling proactive maintenance, improving patient outcomes and reducing medical equipment downtime. Generative AI enables personalised treatment plans and ensures regulatory compliance, while cloud-based analytics offers scalable, cost-effective solutions for large volumes of data and real-time monitoring. Big data insights help drive innovation by identifying unmet clinical needs. Data analytics in commercial effectiveness provides market insights and helps inform product development.

The primary aim of this unit is to provide students with the critical skills necessary for collecting, analysing, interpreting and presenting data effectively within the MedTech sector. Students will explore various data sources, learn advanced data visualisation techniques and leverage data-driven insights to improve decision-making processes and business outcomes. This knowledge is vital for individuals aiming for careers in medical research, healthcare data analysis and strategic decision-making within the MedTech industry.

The unit covers the fundamental principles of business informatics, such as types of data analytics (descriptive, predictive and prescriptive), methodologies for data collection, data cleaning techniques, and ethical considerations regarding data use. In this highly practical unit, students will plan a data analysis methodology for a given MedTech scenario. They will investigate a range of analytical tools and techniques as well as the various decision-making frameworks available. Finally, students will apply their knowledge in implementing the data analysis plan for the MedTech scenario, considering the challenges and ethical issues involved. They will use the results of their data analysis plan to develop realistic, data-driven recommendations for the MedTech business scenario.

On completion of this unit, students will acquire a comprehensive understanding of analytical reasoning, data interpretation and strategic decision-making in the MedTech industry. These skills will help students prepare for a range of careers that use data analytics, in roles such as Healthcare Data Analyst, Medical Business Intelligence Specialist and Research Data Coordinator.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Examine the fundamental principles of business informatics and their application in decision-making within the MedTech industry

LO2 Plan a data analysis methodology for a given scenario within the MedTech sector

LO3 Implement a data analysis plan for a given scenario within the MedTech sector

LO4 Develop data-driven recommendations to inform decision-making for a given business scenario within the MedTech industry.

Essential Content

LO1 **Examine the fundamental principles of business informatics and their application in decision-making within the MedTech industry**

Fundamental principles of business informatics:

e.g. Data integration: ensuring seamless integration of data from various sources, such as patient records, clinical trials and device performance

e.g. Interoperability: facilitating communication between different systems and devices to ensure data consistency and accessibility

e.g. Data quality: maintaining high standards of data accuracy, completeness and reliability to support informed decision-making

e.g. User-centred design: developing systems and solutions that meet the specific needs of healthcare professionals and patients

e.g. Regulatory compliance: adhering to industry standards and regulations, such as ISO 13485 and FDA guidelines, to ensure safety and efficacy

e.g. Security and privacy: implementing robust security measures to protect sensitive health data and ensure patient privacy.

Data analytics methods:

Descriptive analytics: e.g. historical data trends, patterns, data aggregation, summarisation, visualisation, dashboards

Predictive analytics: e.g. forecasting, statistical modelling, machine learning algorithms, risk assessment

Prescriptive analytics: e.g. optimisation techniques, simulation models, recommendations, decision support systems.

MedTech applications of business informatics:

Patient care: e.g. real-time monitoring, predictive diagnostics, electronic health records (EHR) management, telemedicine analytics, patient outcomes

Resource management: e.g. inventory optimisation, medical equipment maintenance (e.g. predicting failures, scheduling maintenance, reducing downtime), scheduling, patient flow management

Medical research: e.g. data mining in clinical trials, genetic data analysis, drug interaction modelling

Market analysis: e.g. trend forecasting, market segmentation, competitor analysis.

Device maintenance: e.g. forecasting device failures and scheduling proactive maintenance, reducing downtime and extending the lifespan of medical devices

Generative AI: e.g. personalised treatment plans and regulatory compliance, documentation automation

Cloud-based analytics: e.g. scalability, real-time monitoring

Big data integration: e.g. comprehensive insights from patient records, clinical trials, medical devices; innovation

Commercial effectiveness: e.g. market insights, product development.

LO2 **Plan a data analysis methodology for a given scenario within the MedTech sector**

Objectives:

Definition of analysis goals, formulation of measurable questions.

Data selection and preparation:

Collection methods, e.g. clinical trials, EHRs, administrative data, IoT data, public health records, usage logs

Best practices: objective alignment, appropriate technological tools, data security and privacy.

Data quality dimensions:

Importance of accuracy, completeness, timeliness, consistency, validity

Dataset preparation: cleaning and pre-processing steps, e.g. removing duplicates, correcting errors, handling missing values

Impact of poor data quality on decision-making and public health outcomes.

Analytical tools:

Introduction to software tools, e.g. spreadsheets, Tableau, Power BI

Statistical programming languages, e.g.

- R, e.g. data analysis, visualisation, biostatistics, epidemiology
- Python, e.g. data manipulation, statistical analysis, machine learning, predictive analytics
- SAS, e.g. advanced analytics, multivariate analysis, business intelligence, data management
- SPSS, e.g. statistical analysis, healthcare research, survey research, observational studies, clinical trials

Stata, e.g. data management, statistical analysis, graphical representation, longitudinal data analysis, survival analysis, meta-analysis

Tableau, e.g. data visualisation, interactive dashboards, patient outcomes, healthcare operations, research

Excel, e.g. data entry, management, basic statistical analysis, preliminary analysis, visualisation

MATLAB, e.g. numerical computing, algorithm development, signal processing, image analysis, medical device modelling

JMP, e.g. data visualisation, statistical analysis, quality control, reliability analysis, design of experiments

Minitab, e.g. quality improvement, statistical education, process improvement, Six Sigma projects

Language functionalities: data cleaning, input validation, visualisation, statistical functions.

Frameworks for decision-making:

Evidence-based decision-making framework (EBDM), Plan-Do-Check-Act (PDCA), SWOT Analysis, Monte Carlo Simulation, Six Sigma DMAIC

Appropriate framework selection

Exploratory data analysis (EDA): use statistical methods and visualisation tools to understand data patterns and distributions

Hypothesis testing: formulate and test hypotheses to determine the statistical significance of observed effects

Model building: develop predictive models to identify key factors influencing recovery times.

Stakeholder engagement:

Identification, involvement planning, understanding needs and expectations.

LO3 Implement a data analysis plan for a given scenario within the MedTech sector

Management of the data analysis plan:

Project management, e.g. timeline adherence, application of methodologies and tools, KPI identification, milestones, analysis plan issue and risks register, contingency planning, resource allocation.

Implementing a data analysis plan:

Set up infrastructure: e.g. IT infrastructure, databases, analytics software, data storage solutions

Data collection: e.g. protocols, ethical and regulatory compliance

Data cleaning and integration: e.g. ETL processes

Conduct EDA: e.g. Python, R, specialised analytics software

Build and test models: e.g. machine learning algorithms, cross-validation techniques

Generate insights: e.g. model outputs, actionable insights, trends identification

Communicate results: e.g. dashboards, reports, presentations.

Post implementation actions:

Plan evaluation: e.g. pre- and post-implementation analysis, performance tracking

Insight generation: e.g. identifying patterns, trends, correlations, anomalies

Evidence-based analysis: e.g. empirical, statistical, predictive techniques.

Challenges in data-driven decision-making:

Common challenges: e.g. data limitations, stakeholder resistance, integrating quantitative and qualitative data

Risk management: identifying and mitigating risks associated with strategic decisions.

Ethical considerations:

Data privacy, informed consent, transparency, user impact, bias, fair use of predictive models.

Analytical tools specific to MedTech:

Patient care analytics: e.g. Cerner, Epic

Resource management: e.g. SAP ERP for healthcare

Research and market analysis: e.g. SAS, SPSS, Microsoft BI.

LO4 **Develop data-driven recommendations to inform decision-making for a given business scenario within the MedTech industry**

Developing data-driven recommendations:

Analyse market data: e.g. market trends, customer feedback

Identify key drivers: e.g. market adoption factors

Develop strategies: e.g. device features enhancement, pricing optimisation, marketing improvement

Implement changes: e.g. cross-functional team collaboration; formulating actionable, data-driven recommendations based on analysis

Monitor impact: e.g. track market adoption impact, strategies adjustment

Report outcomes: e.g. stakeholder communication, highlighting successes and areas for improvement.

Communication and reporting skills:

Presentation skills: e.g. structure, narrative, clarity, engagement

Tone: e.g. formal, informal, conversational

Written communication: e.g. structure: introduction, body, conclusion, logical flow, conciseness

Follow-up: e.g. next steps, implications, strategic alignment

Data visualisation: e.g. visual storytelling, charts, graphs, dashboards; creating intuitive visualisations for stakeholder interpretation

Equality, diversity and inclusion (EDI) considerations: e.g. viewer characteristics, cultural diversity, communication methods, appropriate content, appropriate imagery, participation modules, audience reactions, inclusivity features.

Feedback mechanisms:

Incorporating stakeholder feedback, iterating improvement, ongoing evaluation.

Learning Outcomes and Assessment Criteria

Pass	Merit	Distinction
LO1 Examine the fundamental principles of business informatics and their application in decision-making within the MedTech industry		
P1 Examine, using a range of real-world case studies, the fundamental principles of business informatics and data analytics methods within the MedTech industry. **P2** Explore, using a range of real-world case studies, the application of business informatics to decision-making in the MedTech sector.	**M1** Analyse, using a range of real-world case studies, the effectiveness of the application of business informatics to decision-making within the MedTech sector.	**D1** Critically evaluate, using a range of real-world case studies, the effectiveness of the application of business informatics to decision-making within the MedTech sector.

Pass	Merit	Distinction
LO2 Plan a data analysis methodology for a given scenario within the MedTech sector		**LO2, LO3 and LO4** **D2** Critically evaluate the data analysis plan and the data driven recommendations obtained to inform decision-making for a given business scenario within the MedTech industry.
P3 Review the range of analytical tools and decision-making frameworks that can be used to develop a data analysis methodology for a given scenario within the MedTech sector. **P4** Plan a data analysis methodology for a given scenario within the MedTech sector.	**M2** Justify the data analysis methodology, the selection of analytical tools and decision-making frameworks used for a given scenario within the MedTech sector.	
LO3 Implement a data analysis plan for a given scenario within the MedTech sector		
P5 Review the ethical considerations and challenges in developing a data analysis plan for a given scenario within the MedTech sector. **P6** Implement a data analysis plan for a given scenario within the MedTech sector, including plan management and post-implementation actions.	**M3** Justify the data analysis plan for a given scenario within the MedTech sector, including plan management and post-implementation actions.	
LO4 Develop data-driven recommendations to inform decision-making for a given business scenario within the MedTech industry		
P7 Develop data-driven recommendations to inform decision-making for a given business scenario within the MedTech industry. **P8** Present the data driven recommendations to a range of relevant stakeholders to gather feedback.	**M4** Analyse the stakeholder feedback obtained to review and optimise the data driven recommendations developed from the data analysis plan.	

Recommended Resources

Textbooks

Ahmed, M. and Pathan, A.-S.K. eds. (2018) *Data Analytics: Concepts, Techniques, and Applications.* 1st Ed. Baco Raton: CRC Press.

Burk, S. and Miner, G.D. (2020) *It's All Analytics!: The Foundations of Al, Big Data and Data Science Landscape for Professionals in Healthcare, Business, and Government*. Baco Raton: CRC Press.

Chakraborty, C., Ghosh, U., Ravi, V. and Shelke, Y. eds. (2021) *Efficient Data Handling for Massive Internet of Medical Things: Healthcare Data Analytics*. Cham: Springer International Publishing.

Jena, O.P., Bhushan, B. and Kose, U. eds. (2022) *Machine Learning and Deep Learning in Medical Data Analytics and Healthcare Applications*. Baco Raton: CRC Press.

Moreira, J., Carvalho, A. and Horvath, T. (2018) *A General Introduction to Data Analytics*. Hoboken: John Wiley & Sons.

Pandey, R., Maurya, P. and Chiong, R. eds. (2023) *Data Modelling and Analytics for the Internet of Medical Things*. Baco Raton: CRC Press.

Websites

www://asana.com/resources/data-driven-decision-making	Data-driven decision making: A step-by-step guide (Article)
www.collibra.com/blog/the-6-dimensions-of-data-quality	The 6 data quality dimensions with examples (Blog)
www.ibm.com/think/topics/data-driven-decision-making	What is data-driven decision-making? (Article)
www://insightsoftware.com/blog/comparing-descriptive-predictive-prescriptive-and-diagnostic-analytics/	Comparing Descriptive, Predictive, Prescriptive, and Diagnostic Analytics (Blog)
www.researchgate.net/publication/337086700_Business_Informatics_Principles	Business Informatics Principles (Article)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 408: Designing a MedTech Project

Unit 501: Data Management and Cybersecurity

Unit 502: Computer Systems Validation

Unit 503: Managing a MedTech Project

Unit 509: ISO Standard Auditing for Medical Devices

Unit 513: Quality by Design.

Unit 505: Manufacturing Processes

Unit code: **L/651/7111**

Unit level: **5**

Credit value: **15**

Introduction

The medical technology (MedTech) industry is a dynamic and vital sector focused on the design, development and production of medical devices that can have a significant impact on patient care. This unit on Manufacturing Processes is designed to give students an overview of medical device manufacturing, emphasising the importance of these processes in ensuring product quality, regulatory compliance, cost-efficiency and, ultimately, patient safety. This unit is essential for students aiming to pursue a career in the manufacturing side of the MedTech industry, offering the core knowledge required to understand such a complex and highly regulated environment.

The primary aim of this unit is to provide students with an in-depth understanding of the fundamental manufacturing processes involved in the production of medical devices. Through detailed case study analysis, students will learn to develop and review manufacturing methods, ensuring they meet stringent quality and safety standards. This approach will help equip students with the necessary skills to address real-world manufacturing challenges in the MedTech sector.

This unit covers a wide range of manufacturing processes critical to MedTech. Key focus areas include the importance of manufacturing processes for medical devices, common methods such as injection moulding, CNC machining, 3D printing and laser cutting, and the significance of material selection and cleanliness in manufacturing environments. Each topic is designed to build on the previous one, providing a progressive and comprehensive learning experience. The unit content builds to a practical component, where students are to develop a manufacturing process for an identified medical device, ensuring they adhere to regulatory standards and meet market demands.

On successful completion of this unit, students will have acquired a thorough understanding of the processes involved in the manufacturing of medical devices, including process development, quality control and regulatory compliance. They will be able to evaluate manufacturing processes, justify the selection of appropriate equipment and evaluate the importance of product cleanliness and safety. These skills are directly applicable to a range of job roles in MedTech, such as Process Engineer, Quality Assurance Specialist, Production Manager and Regulatory Affairs Manager.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Discuss the importance of manufacturing processes for medical devices

LO2 Review the common manufacturing methods used for medical devices

LO3 Explain the importance of material selection and product cleanliness in the manufacturing of medical devices

LO4 Develop a manufacturing process for an identified medical device.

Essential Content

LO1 **Discuss the importance of manufacturing processes for medical devices**

Quality assurance concepts:

Consistency: e.g. product uniformity, repeatability, reliability assurance, performance stability

Reliability: e.g. dependability, robustness, durability, life cycle consistency

Error reduction: e.g. defect minimisation, error proofing, process validation, root cause analysis.

Regulatory compliance:

Readiness: regulatory bodies (MHRA, EMA, TGA, FDA), public trust building, corporate reputation protection

ISO 13485: medical devices – QMS compliance, international standards, procedural adherence

CE marking: Conformité Européenne, European regulatory requirements, certification process.

Cost-efficiency:

Production optimisation: e.g. lean manufacturing, Six Sigma, process improvement, waste reduction; mass production scalability, production cost management, design for manufacturability (DFM) principles, design for assembly (DFA) integration, production throughput optimisation, assembly line efficiency maximisation

Waste minimisation: e.g. recycling protocols, sustainability, resource efficiency, eco-friendliness

Resource allocation: e.g. cost control, budget management, financial optimisation, investment return.

Manufacturability concepts in the design stage:

Design considerations: e.g. mass manufacture: cost-effectiveness, manufacturing scalability, profitability, economic viability

Assembly: e.g. ease of assembly, work instructions, consistency, maintenance requirements, repairability

Servicing: e.g. future servicing, maintenance protocols, post-market support, product longevity

Prototyping versus mass production: e.g. cost considerations, effort assessment, scalability challenges, unit economics.

Fundamentals of patient safety:

Device functionality: e.g. performance reliability, operational accuracy, usability, functionality tests, therapeutic effectiveness

Harm prevention: e.g. safety standards, patient protection, risk minimisation, hazard controls

Risk management: e.g. risk assessment, hazard analysis, mitigation and reduction strategies, emergency protocols.

Innovation:

Advanced manufacturing technologies: e.g. automation, robotics, IoT (Internet of Things), smart factories

Process improvement: e.g. continuous improvement, agile manufacturing, Kaizen, innovation strategies

New product introduction: e.g. product life cycle management, pilot production, scaling strategies, market launch.

LO2 **Review the common manufacturing methods used for medical devices**

Injection moulding theory:

High-pressure injection: e.g. melted polymer plastics, mechanical properties, desired colours, material flow

Cavity mould: e.g. steel, aluminium, final shape specifications, mould design, cooling systems, mould release

Pros: e.g. established method (e.g. global prevalence, reliable service providers, industry standards); cost-effective at high volumes (e.g. large-scale production, unit cost reduction, volume discounts); fast process (e.g. high throughput, cycle time, production efficiency, automated systems); complex shapes (e.g. intricate geometry, fine details, surface finish, mould complexity)

Cons: e.g. high upfront tooling costs (e.g. tooling investment, complexity, initial setup costs, return on investment); long lead time (e.g. tool creation, CNC machining of moulds, production preparation, supply chain delays); hidden costs (e.g. tool modifications, error rectification, shipping expenses, project management); fixed part shape (e.g. design rigidity, post-tool modifications, rework costs, product iterations)

Other moulding processes: e.g. compression moulding (e.g. material preparation, moulding, pressure application, curing, extraction, post-processing); coating (e.g. coating selection, pre-treatment, coating application, curing, post-treatment).

CNC machining concepts:

High precision: e.g. subtractive process, material removal, block material, wood, metal, plastic, composite

Material removal: e.g. detailed shaping, complex geometries, high tolerances, multi-axis machining

Pros: e.g. established process (e.g. specialist providers, global availability, widespread industry use); high tolerances (e.g. precision parts, critical components, implants, surgical instruments); small volume production (e.g. custom parts, patient-specific implants, economical small runs); fast turnaround (e.g. short lead times, days instead of weeks, rapid prototyping, quick delivery)

Cons: e.g. high per unit costs (e.g. economical for small runs, cost-effective threshold, unit pricing); time-intensive (e.g. slow production, one-part-at-a-time manufacturing, operational delays); material waste (e.g. subtractive nature, scrap management, recycling exotic materials, high costs).

3D printing concepts:

Additive process: e.g. layer deposition, polymer, metal, clay, concrete, glass, photopolymer, powder bed fusion

3D printing types: e.g. SLA, SLS, FDM, DMLS, EBM (Electron Beam Melting), material jetting, binder jetting

Pros: e.g. low cost (e.g. in-house design, design iterations, rapid turnaround, prototyping affordability); fast operation (e.g. hours for parts, quick adjustments, iterative development, production flexibility); complex geometries (e.g. intricate shapes, custom designs, unique capabilities, organic shapes); customisation (e.g. individual patient needs, personalised devices, multiple parts, mass customisation)

Cons: e.g. surface finish (e.g. dimensional accuracy, internal parts, finishing requirements, secondary processing); material strength (e.g. layering variations, load applications, force resistance, structural integrity); high-volume production (e.g. slow pace, error-prone prints, restarts, production scaling limitations); printer size limitations (e.g. size constraints, part dimensions, print volume envelope, machine capacity).

Laser-cutting concepts:

High-powered laser: e.g. focused beam, cutting path, programmed designs, CNC laser cutters, fibre lasers

Flat sheet materials: e.g. polymers, metals, composite materials, ceramics, textiles, multilayer sheets

Pros: precision (e.g. high accuracy, repeatability, intricate designs, exact dimensions, minimal thermal effect); fast setup (e.g. quick changeover, multiple material cuts, efficiency, production flexibility, speed); in-house capability (e.g. machine purchase, part creation, third-party dependence reduction, cost savings)

Cons: flat materials (e.g. part limitations, 2D geometries, design constraints, material thickness); material thickness (e.g. low-cost lasers, cutting depth, power limitations, industrial-grade options).

Assembly process theory:

Automated assembly: e.g. robotics, high throughput, precision alignment, automated systems, smart assembly

Manual assembly: skilled labour, small batch production, complex processes, human factors, craftsmanship

Quality control: e.g. in-process inspection, defect identification, compliance verification, testing protocols.

LO3 **Explain the importance of material selection and product cleanliness in the manufacturing of medical devices**

Material theory:

Metals: e.g. stainless steel (e.g. corrosion resistance, strength, antibacterial properties, biocompatibility, machinability), titanium (e.g. lightweight, biocompatibility, high strength-to-weight ratio, corrosion resistance, osseointegration)

Polymers: e.g. polyethylene (e.g. versatility, wear resistance, low friction, impact resistance, biocompatibility, flexibility), ABS (e.g. toughness, impact resistance, good processability, thermoplastic properties, industrial use)

Ceramics: high temperature resistance, electrical insulation, hardness, wear resistance, biocompatibility, inertness

Composites: material combinations, enhanced properties, application-specific uses, laminate structures, hybrid materials.

Fundamentals of clean room standards:

ISO classes: e.g. Class 1 to Class 9, airborne particulate count, contamination control, cleanliness certification, validation

Contamination control: e.g. particle filtration, environmental monitoring, filtration efficiency, contamination logs, air quality control

Air quality: e.g. HEPA filters, controlled environments, air exchange rates, laminar flow, clean air flow, air pressure differentials

Personnel protocols: e.g. gowning, de-gowning, hygiene standards, contamination prevention, cleanroom attire, behavioural protocols.

Product cleanliness concepts:

Cleanliness requirements: e.g. sanitary requirements (e.g. medical device specifications, cleanliness levels, sanitary standards, regulatory guidelines)

Manufacturing processes: e.g. ISO 13485 compliance, clause 7.5.2, clause 7.5.5, contamination control, cleanliness protocols.

Material selection theory:

Biocompatibility: e.g. interaction (e.g. blood, tissues, bodily fluids, biological response, immune system)

Toxicology factors: e.g. toxicity, irritation, allergic reactions, inflammation, hypersensitivity, compatibility testing

Testing: e.g. biocompatibility assessment, cytotoxicity tests, in vivo studies, in vitro simulations, safety validation

Biocompatibility standards: ISO 10993.

LO4 **Develop a manufacturing process for an identified medical device**

Scenario planning and risk assessment:

Functional requirements: e.g. performance criteria, operational parameters, user needs, technical specifications, design constraints

Design considerations: e.g. ergonomics, usability, safety features, user experience, human factors, regulatory compliance

Usage context: e.g. clinical environment, user interaction, device application, healthcare setting, patient demographics

Risk assessment: e.g. risk classification (e.g. low, moderate, high); hazard identification procedures (e.g. biological, mechanical, electrical risks); design failure mode and effects analysis (DFMEA) frameworks, hazard severity ranking, risk mitigation matrices, product life cycle risk maps.

Pre-manufacturing considerations:

Workflow steps: e.g. sequential processes, task definition, operational flow, process mapping, step-by-step guides

Equipment selection: e.g. materials, machinery, tools, fixtures, production setup, capital equipment, operational readiness

Process optimisation: e.g. efficiency assessment, productivity enhancement, bottleneck identification, cost reduction, value stream mapping, scrap and waste management procedures

Design for assembly (DFA) principles: e.g. maintenance accessibility planning, life cycle cost evaluation, serviceability design integration, scalability to mass production, prototyping versus production differentiation, manufacturability assessment during design stage

Process optimisation: e.g. efficiency assessment, productivity enhancement, bottleneck identification, cost reduction, value stream mapping.

Process documentation:

Process qualification: e.g. Installation Qualification (IQ) documentation, Operational Qualification (OQ) verification, Performance Qualification (PQ) analysis

Process management: e.g. statistical process control (SPC) methods, CAPA systems integration, Kaizen continuous improvement cycles, Six Sigma defect reduction programmes, root cause analysis tools.

Quality management plan:

Inspection points: e.g. critical checkpoints, inspection timing, defect detection, sampling plans, testing protocols; finished goods inspection protocols (e.g. first article inspection (FAI), final inspection sampling)

Testing standards: e.g. regulatory standards, performance benchmarks, compliance requirements, validation metrics

Compliance documentation: e.g. record keeping, traceability, audit trails, regulatory submissions, documentation systems, non-conformance material reports (NCMRs).

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Discuss the importance of manufacturing processes for medical devices</td><td rowspan="2"></td></tr>
<tr><td>P1 Discuss, using a range of real-world case studies, the importance of manufacturing processes for medical devices.</td><td>M1 Analyse, using a range of real-world case studies, the importance of manufacturing processes for medical devices.</td></tr>
<tr><td colspan="2">LO2 Review the common manufacturing methods used for medical devices</td><td rowspan="4">LO2 and LO3
D2 Critically evaluate the importance of material selection, product cleanliness and manufacturing methods used in the manufacturing of a range of real-world medical devices.</td></tr>
<tr><td>P2 Review, using a range of real-world case studies, the manufacturing methods of injection moulding and CNC machining used for medical devices.
P3 Explore, using a range of real-world case studies, the manufacturing methods of 3D printing and laser-cutting machining used for medical devices.</td><td>M2 Analyse, using a range of real-world case studies, the common manufacturing methods used for medical devices.</td></tr>
<tr><td colspan="2">LO3 Explain the importance of material selection and product cleanliness in the manufacturing of medical devices</td></tr>
<tr><td>P4 Explain, using a range of real-world case studies, the importance of material selection in the manufacturing of medical devices.
P5 Assess, using a range of real-world case studies, the importance of product cleanliness in the manufacturing of medical devices.</td><td>M3 Justify, using a range of real-world case studies, the importance of material selection and product cleanliness in the manufacturing of medical devices.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Develop a manufacturing process for an identified medical device		
P6 Develop a manufacturing process for an identified medical device. **P7** Present the manufacturing process to a range of relevant stakeholders to gather feedback.	**M4** Justify the decisions made in the development of the manufacturing process, based on your own assessment as well as the stakeholder feedback.	**D3** Critically evaluate the effectiveness of the developed manufacturing process, identifying strengths and areas for improvement.

Recommended Resources

Textbooks

Azarkaman, A., Deilamani, P.R. and Ghorbani, N. (2022) *Medical Devices Engineering Textbook 1.* Nobel TM.

Evans, M. (2022) *Optimisation of Manufacturing Processes: A Response Surface Approach*. Baco Raton: CRC Press.

Gibson, I., Rosen, D., Stucker, B. and Khorasani, M. (2021) *Additive Manufacturing Technologies*. Vol.17 (pp.160-186). Cha: Springer.

Rana, G., Khang, A., Sharma, R., Goel, A.K. and Dubey, A.K. eds. (2021) *Reinventing Manufacturing and Business Processes through Artificial Intelligence*. Baco Raton: CRC Press.

Youssef, H.A., El-Hofy, H.A. and Ahmed, M.H. (2023) *Manufacturing Technology: Materials, Processes, and Equipment*. 2nd Ed. Baco Raton: CRC Press.

Websites

www.ansys.com/en-gb/blog/design-for-manufacturing-best-practices	Ansys Design for Manufacturing (DfM) Best Practices (Blog)
www.apriori.com/design-for-manufacturability/	APriori A Guide to Design for Manufacturability (Article)
www.designreview.byu.edu/collections/a-brief-overview-of-manufacturing-processes	BYU A Brief Overview of Manufacturing Processes (Review)
www.devicelab.com/blog/material-selection-guide-for-medical-device-development/	DeviceLab Material Selection Guide for Medical Device Development (Article)
www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation	FDA Overview of Device Regulation (Article)

www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements	UK Gov Medical devices: how to comply with legal requirements in Great Britain (Guidance)
www.hubs.com/knowledge-base/medical-device-manufacturing/	Protolabs Network Medical device manufacturing: Best practices, applications and regulations (Article)
www.iso.org/iso-13485-medical-devices.html	International Organization for Standardization ISO 13485 Medical devices (Resource)
www.mecart-cleanrooms.com/learning-center/cleanroom-classifications-iso-8-iso-7-iso-6-iso-5/	MECART Clean Room Classifications (ISO 8, ISO 7, ISO 6, ISO 5) (Article)
www.meddeviceonline.com/resource/medical-device-manufacturing	Med Device Online Medical Device Manufacturing (Resource)
medicaldevicehq.com/articles/process-validation-documentation-terminology-and-explanations	MedicalDeviceHQ Process validation documentation: terminology and explanations (Blog)
www.sciencedirect.com/science/article/abs/pii/S1526612523009726	ScienceDirect Revolutionizing manufacturing: A comprehensive overview of additive manufacturing processes, materials, developments and challenges (Article)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 403: Risk Management (ISO 14971)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 507: DevOps Engineering

Unit 510: Good Practices in MedTech

Unit 513: Quality by Design

Unit 515: Advanced Manufacturing.

Unit 506: Understanding User Needs

Unit code: **M/651/7112**

Unit level: **5**

Credit value: **15**

Introduction

In the constantly changing landscape of medical technology (MedTech), understanding user needs is paramount for the development of effective, safe and user-friendly products. This unit is designed to equip students with a comprehensive understanding of the importance of user needs analysis in the MedTech field. The focus is on ensuring that medical devices and systems align with the specific needs of diverse user groups, thereby enhancing their usability, safety and accessibility.

The primary aim of this unit is to provide students with a deep understanding of the core concepts and methodologies involved in user needs analysis within the MedTech sector. This knowledge is crucial for ensuring that MedTech products meet the high standards required by both regulatory bodies and end-users, ultimately leading to more successful adoption and utilisation of these technologies.

The unit covers a broad array of topics essential for understanding and applying user needs analysis in the MedTech industry. Key areas of focus include defining user needs, identifying and segmenting user groups, exploring the various stakeholders involved, and understanding the regulatory frameworks that govern MedTech products. Students will also explore primary and secondary research techniques for gathering user insights, usability testing, data validation methods, and the impact of user needs on product usability and regulatory compliance. The unit also includes a practical component, where students will apply their knowledge to design an effective user needs assessment for a MedTech scenario.

On successful completion of this unit, students will have developed a robust set of skills in user needs analysis, critical for roles in MedTech product development, user experience design and regulatory compliance. Students will be able to design detailed user needs assessments for specific MedTech scenarios, preparing them for real-world challenges in the development, implementation and management of medical technologies. These skills are directly applicable to a range of positions within the MedTech industry, such as user research, product management and regulatory affairs.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explain the concepts of user needs analysis and their role in MedTech

LO2 Review a range of methodologies for collecting and validating user insights

LO3 Assess the ways in which user needs analysis can have an impact on MedTech products

LO4 Design a user needs assessment for an identified MedTech scenario.

Essential Content

LO1 Explain the concepts of user needs analysis and their role in MedTech

Core concepts:

User needs definition: e.g. safety, usability, affordability, accessibility, efficiency

Stakeholders: e.g. patients, caregivers, clinicians, technicians, procurement teams

Regulatory frameworks: MDR, IVDR, FDA, ISO 13485, ISO 9001, ISO 14971

Risk of misalignment: e.g. product recalls, adoption failure, user dissatisfaction, increased support costs

Risks of ignoring user needs: e.g. product failure, recalls, reputational damage.

User identification and segmentation:

Primary users: e.g. patients, healthcare professionals, caregivers, lab technicians

Secondary users: e.g. procurement teams, maintenance engineers, hospital IT teams

Vulnerable populations: e.g. paediatric, elderly, disabled, non-native language users

Contextual factors: e.g. clinical versus home use, emergency care, remote monitoring.

User groups and their needs:

Healthcare professionals (HCPs): e.g. clinical workflow integration such as time efficiency, data interoperability, electronic health records (EHRs); usability challenges (e.g. alarm fatigue, cognitive overload, information fragmentation); training and education needs (e.g. simulation-based training, minimal learning curve, competency testing)

Patients and caregivers: e.g. home healthcare and self-monitoring (e.g. wearables, chronic disease management, medication adherence); accessibility and inclusivity (e.g. sensory impairments, physical limitations, mental health considerations); psychological and emotional considerations (e.g. trust in medical technology, health literacy, adherence behaviours)

Public health and systemic stakeholders: e.g. health system efficiency (e.g. resource optimisation, cost reduction, patient throughput); regulatory and policy considerations (e.g. compliance frameworks, liability concerns, evidence-based standards); private sector and insurers (e.g. return on investment (ROI), reimbursement models, financial sustainability).

Concepts of user needs analysis:

Demographics: e.g. age, gender, income, education, occupation, cultural background

Psychographics: e.g. attitudes, values, lifestyle, motivations, health beliefs

Behaviour Patterns: e.g. device usage frequency, task complexity, error rates, satisfaction levels, compliance behaviour

Goals: e.g. medical objectives, everyday goals, long-term aspirations, treatment outcomes, health maintenance

Pain points: e.g. usability issues, physical discomfort, cognitive load, emotional stress, accessibility barriers

Motivations: e.g. health improvement, convenience, time savings, cost-effectiveness, emotional support.

LO2 **Review a range of methodologies for gathering, recording and validating user insights**

Primary research techniques:

User Interviews: e.g. structured, semi-structured, unstructured approaches, clinical interviews, interview guide, probing questions

Surveys and questionnaires: e.g. quantitative and qualitative insights, Likert scales, demographic analysis, question types (e.g. scaling, closed-ended questions, open-ended questions); focus groups and workshops (e.g. stakeholder engagement, participatory design, co-creation, participant selection, discussion guide, facilitation techniques, group dynamics, data capture methods)

Shadowing and observations: e.g. contextual inquiry, clinical setting analysis, workflow mapping

Ethnographic studies: e.g. field observation, contextual inquiry, participant observation, note taking, video recording.

Secondary research and data-driven insights:

Medical literature review: e.g. systematic reviews, meta-analysis, peer-reviewed studies

Market research: e.g. competitive landscape, emerging trends, consumer behaviour analytics

Regulatory databases: e.g. adverse event reports, incident tracking, failure analysis

Usability testing and validation

Prototype testing: e.g. low-fidelity versus high-fidelity prototypes, wireframing, iterative design

Heuristic evaluation: e.g. usability scorecards, expert reviews, benchmarking standards

Simulated clinical environments: e.g. real-world scenario testing, patient feedback, HCP validation.

Data collection and validation tools and techniques:

Questionnaires: e.g. design principles, validation, scaling, reliability, distribution methods

Observation checklists: e.g. standardisation, behaviours, tasks, environment, time sampling

Real-world evidence (RWE): e.g. patient-reported outcomes, clinical trial data, electronic health records (EHRs)

Pilot studies and trials: e.g. beta testing, iterative prototyping, controlled environment trials

User story development: e.g. scenario planning, journey mapping, pain point analysis

AI-driven insights: e.g. sentiment analysis, automated survey processing, structured qualitative data.

Feedback channels and life cycle tracking:

Post-market surveillance (PMS): e.g. ISO and MDR/IVDR compliance, adverse event reporting

Customer support logs: e.g. identifying usability challenges, recurring errors

Patient and public involvement (PPI): e.g. ethics panels, structured engagement, peer review

Regulatory-driven documentation: e.g. compliance records, user testing reports, risk logs.

LO3 Assess the ways in which user needs analysis can have an impact on MedTech products

User needs – device usability:

User experience: interface design (e.g. visual appeal, layout consistency, colour schemes, iconography, graphics); accessibility (e.g. inclusive design, screen readers, high-contrast modes, keyboard navigation, multilingual support); user interface (UI) (e.g. buttons, menus, dialogs, input fields, widgets)

End-user comfort: ergonomics (e.g. handheld devices, comfortable grips, lightweight, adjustable stand); physical interaction (e.g. touch sensitivity, gesture control, wearable compatibility, haptic feedback)

User feedback: surveys, focus groups, questionnaires, usability testing

Performance: efficiency, e.g. load time, speed, resource management, optimisation, battery.

Impact of user needs on usability:

Personalisation: user profiles (e.g. demographics, medical history, preferences, usage patterns, account settings); tailored features (e.g. specific tools, personalised dashboards, custom alerts, user-specific reports); adaptive functionalities (e.g. machine learning, predictive analytics, context-aware services, dynamic adjustments)

Safety: hazard mitigation (e.g. risk assessments, safety audits, compliance standards, regulatory guidelines, monitoring); error reduction (e.g. user errors, automated corrections, input validation, feedback loops, verification processes); safety protocols (e.g. emergency procedures, safety instructions, alarm systems, incident reporting, compliance documentation).

User needs – regulation compliance:

Patient safety: risk management (e.g. hazard analysis, risk assessment, mitigation strategies, safety measures, patient protection); clinical outcomes (e.g. efficacy, treatment success, health improvement, patient recovery rates, outcome metrics); data privacy (e.g. confidentiality, protected health information (PHI), data encryption, user consent, anonymity)

Usability requirements: user-centred design (e.g. user feedback, usability testing, ergonomic design, user preferences, intuitive interfaces); accessibility standards (e.g. ADA compliance, universal design, assistive technologies, inclusive features, multilingual support); documentation requirements (e.g. user guides, training manuals, compliance documentation, logging procedures, data records).

Impact of user needs on regulatory compliance:

Device performance: performance metrics (e.g. accuracy, reliability, durability, performance benchmarks, operational efficiency); labelling and instructions (e.g. clear instructions, use guidelines, safety warnings, compliance symbols, packaging information); post-market surveillance (e.g. usage data, incident reporting, recalls, corrective actions, continuous monitoring)

Compliance frameworks, e.g. NICE, ESF

Human factors engineering: usability engineering (e.g. task analysis, usability evaluation, cognitive load, efficiency, user errors); biocompatibility (e.g. material safety, skin contact, toxicology, allergens, regulatory testing); ergonomic validation (e.g. user comfort, workflow integration, interface design, physical interaction, user adaptation)

Patient and provider education: training programmes (e.g. user training, certification courses, educational workshops, training modules, e-learning); user manuals (e.g. comprehensive guides, detailed instructions, procedure lists, visual aids, troubleshooting); support services (e.g. helpdesk, customer support, maintenance services, user consultations, feedback mechanisms).

LO4 **Design a user needs assessment for an identified MedTech scenario**

Defining a MedTech concept:

Medical device categories: e.g. diagnostic, therapeutic, monitoring, assistive technology

Intended use and target audience: clinical context, environmental factors, user demographics

Regulatory classification impact: e.g. MDR class I–III, FDA 510(k), de novo pathways, risk-based assessment

Brainstorming: idea generation e.g. creative thinking, group sessions, unconstrained ideation, prioritisation

Design thinking workshops: e.g. empathy mapping, problem definition, ideation, prototyping, testing.

User needs assessment:

Stakeholder mapping: e.g. identifying stakeholders (e.g. end-users, decision-makers, regulatory authorities, investors), interests, influence, power dynamics, stakeholder expectations

Requirement gathering sessions: e.g. stakeholder meetings, user input, need identification, requirement specification, prioritising needs

Use case validation: e.g. real-world scenarios, user feedback, iteration, refinement, validation field trials, pilot studies, feasibility analysis.

User engagement and data collection:

User journey mapping: e.g. pain points, user touchpoints, decision-making processes.

Task analysis: e.g. task breakdown, complexity assessment, efficiency metrics, error tracking, task duration

User observation: e.g. behaviour monitoring, usability issues, task completion rates, interaction patterns, non-verbal cues

A/B testing: e.g. hypothesis formulation, variant comparison, user preference, performance metrics, usability metrics

User satisfaction surveys: e.g. survey design, question types, scoring systems, feedback collection, sentiment analysis

Focus group discussions: e.g. discussion facilitation, user experiences, group insights, common themes, improvement suggestions

Post-use interviews: e.g. experience feedback, usability problems, strengths, areas for improvement, qualitative data.

Data analysis techniques:

Thematic analysis: e.g. theme identification, coding, pattern recognition, theme verification, reporting insights

Quantitative analysis tools: e.g. SPSS, Excel, R, statistical tests, data visualisation.

Synthesising findings and presenting insights:

Gap analysis: e.g. identifying unmet needs, usability barriers, feature enhancement opportunities

Persona development: e.g. user archetypes, behavioural insights, customised interventions

Final report and recommendations: e.g. structured findings, visual data presentation, product roadmap.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explain the concepts of user needs analysis and their role in MedTech</td><td rowspan="5">LO1 and LO2

D1 Critically evaluate, using a range of real-world examples, the various methodologies for collecting and validating user needs, and how these needs play a role in the development of a MedTech product.</td></tr>
<tr><td>P1 Review, using a range of real-world examples, the core concepts of user needs analysis within the MedTech industry.

P2 Explain, using a range of real-world examples, the role of needs analysis for the different user groups within the MedTech industry.</td><td>M1 Analyse, using a range of real-world examples, the impact of user needs analysis in MedTech.</td></tr>
<tr><td colspan="2">LO2 Review a range of methodologies for collecting and validating user insights</td></tr>
<tr><td>P3 Explain, using a range of real-world examples, how primary and secondary research techniques are used for gathering, recording and validating user insights.

P4 Review, using a range of real-world examples, how data collection and validation tools and techniques are used for gathering, recording and validating user insights.</td><td>M2 Analyse, using a range of real-world examples, a range of methodologies for collecting and validating user insights.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Assess the ways in which user needs analysis can have an impact on MedTech products		**LO3 and LO4** **D2** Critically evaluate, using your own analysis and stakeholder review, the effectiveness of the user needs assessment and proposed data analysis methodology in how well it aligns with the business, clinical and regulatory objectives of the MedTech scenario, making recommendations for any future actions.
P5 Explain, using a range of real-world examples, the way a user needs analysis can have an impact on product usability in the MedTech sector. **P6** Discuss, using a range of real-world examples, the way a user needs analysis can have an impact on regulatory compliance in the MedTech sector.	**M3** Analyse, using a range of real-world examples, the ways in which user needs analysis can have an impact on MedTech products.	
LO4 Design a user needs assessment for an identified MedTech scenario		
P7 Design a user needs assessment for an identified MedTech scenario, including methodologies for how the collected data is to be analysed to gain insights. **P8** Review the developed user needs assessment and proposed data analysis methodology with a variety of key stakeholders to identify a range of strengths, weaknesses and areas for improvement.	**M4** Justify, using the contents of the stakeholder review, the choices made in the development of a user needs assessment and proposed data analysis methodology for an identified MedTech scenario.	

Recommended Resources

Textbooks

Albert, B., Tullis T. (2023) *Measuring the User Experience: Collecting, Analyzing, and Presenting Usability Metrics*. Cambridge MA: Morgan Kaufmann.

Britton, C. (2015) *Designing the Requirements: Building Applications that the User Wants and Needs*. Boston: Addison-Wesley Professional.

Cosgriff, P.S. and Memmott, M.J. (2024) *Writing In-House Medical Device Software in Compliance with EU, UK, and US Regulations*. Baco Raton: CRC Press.

Geisler, E. and Heller, O. (2012) *Management of Medical Technology: Theory, Practice and Cases*. Vol. 2. Berlin: Springer Science & Business Media.

Kramme, R., Hoffmann, K.P. and Pozos, R.S. eds. (2011) *Springer Handbook of Medical Technology*. Berlin: Springer Science & Business Media.

Peissner, M., Pollmann, K. and Fronemann, N. (2021) *Collecting and Analyzing User Insights. Handbook of Human Factors and Ergonomics*. (pp.960-971). John Wiley & Sons.

Sleezer, C.M., Russ-Eft, D.F. and Gupta, K. eds. (2014) *A Practical Guide to Needs Assessment*. 3rd Ed. San Franciso: John Wiley & Sons.

Websites

www.devicelab.com/blog/conducting-effective-user-research-for-medical-device-ux-design/	Conducting Effective User Research for Medical Device UX Design (Blog)
www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-developers/all-developers-guidance/researching-user-needs/	NHS Researching user needs (Resource)
www.emjreviews.com/emj-gold/article/catching-the-ever-elusive-insight/	Catching the ever-elusive insight (Article)
www.greenlight.guru/blog/define-your-medical-device-user-needs	8 Questions That Define Your Medical Device User Needs (Blog)
www.mdi.org/blog/post/understanding-user-needs-when-designing-medical-devices/	Understanding User Needs When Designing Medical Devices (Blog)

www.medsci.ox.ac.uk/research/patient-and-public-involvement/section-2-what-is-patient-and-public-involvement	University of Oxford Patient and public involvement, engagement and participation definitions (Resource)
www.merseycare.nhs.uk/about-us/equality-diversity-and-human-rights/protected-characteristics	NHS Protected Characteristics (Blog)
www.netizenexperience.com/blog/user-needs-assessment-for-user-centered-designs/	The Role of User Needs Assessment in Creating User-Centred Designs (Article)
poctinnovators.com/the-evolving-needs-for-clinical-diagnostics-and-medical-devices-in-healthcare/	Point of Care Testing The Evolving Needs for Clinical Diagnostics and Medical Devices in Healthcare (Article)
www.qualtrics.com/en-gb/experience-management/research/customer-needs-analysis/	Customer needs analysis: definition & best practices (Article)
www.td.org/content/atd-blog/can-generative-ai-help-with-needs-analysis	ATD Can Generative AI Help With Needs Analysis? (Blog)
toolbox.eupati.eu/resources/patient-toolbox/introduction-to-patient-involvement-in-medical-devices/	EUPATI Introduction to Patient Involvement in Medical Devices (Article)
www://userpilot.com/blog/user-needs-analysis-example/	User Needs Analysis Example to Help You Identify Customer Needs (Blog)
www.uxpin.com/studio/blog/user-needs/	Top Methods of Identifying User Needs (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 408: Designing a MedTech Project

Unit 503: Managing a MedTech Project

Unit 505: Manufacturing Processes

Unit 509: ISO Standard Auditing for Medical Devices

Unit 512: Marketing and Sales Approaches

Unit 513: Quality by Design.

Unit 507: DevOps Engineering

Unit code: **R/651/7113**

Unit level: **5**

Credit value: **15**

Introduction

The integration of DevOps practices in the MedTech industry represents a paradigm shift towards enhanced collaboration, innovation and efficiency in the development and deployment of medical technologies. The unit is designed to give students a grounding in the principles, tools and methodologies that define DevOps, with a specific focus on their application within the MedTech sector.

The primary aim of this unit is to provide students with a comprehensive understanding of how DevOps can be used within the MedTech industry. Students will explore the fundamental principles of DevOps, including its key practices and tools. By engaging in practical applications, students will design and implement DevOps workflows tailored to specific MedTech scenarios, gaining the skills necessary to lead DevOps initiatives in this dynamic field.

The unit covers a broad range of topics essential for the understanding and application of DevOps in the MedTech industry. Key areas of focus include core DevOps concepts such as continuous integration and continuous deployment (CI/CD), infrastructure as code (IaC), and real-time monitoring. Students will also learn about the tools and technologies that underpin these practices, including Jenkins, Kubernetes, GitHub and Terraform. Additionally, the unit content addresses MedTech-specific applications of DevOps, such as the development of medical software, interoperability standards and disaster recovery mechanisms. Students will apply their knowledge and understanding in designing a practical DevOps methodology for an identified MedTech scenario. By examining real-world case studies as well as the practical design of a DevOps methodology, students will gain an overall view of how DevOps can be effectively integrated into MedTech workflows.

Upon successful completion of this unit, students will have developed a robust set of skills in the theory and application of DevOps methodologies to a range of MedTech scenarios. These skills are directly applicable to various career paths, including such roles as DevOps Engineer, Site Reliability Engineer and Compliance Officer within the MedTech industry.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explore the fundamental principles, tools and practices of DevOps in the MedTech industry

LO2 Explain the benefits and challenges of applying a DevOps methodology to organisations within the MedTech sector

LO3 Analyse the regulatory compliance, security and privacy practices in MedTech DevOps

LO4 Design a DevOps methodology for an identified scenario within the MedTech sector.

Essential Content

LO1 Explore the fundamental principles, tools and practices of DevOps in the MedTech industry

Core DevOps concepts:

Definition and purpose of DevOps: agile principles (e.g. Scrum, Kanban, iterative development); cross-functional collaboration, automation, continuous improvement including feedback loops (e.g. immediate feedback, error tracking, continuous learning); post-mortem analysis, iterative processes

DevOps versus traditional IT: waterfall versus agile, monolithic versus microservices, manual versus automated deployment

Key DevOps pillars: e.g. continuous integration (CI), automated build, version control (including branching strategies, commit history); continuous deployment (CD) including automated testing, staging environments, deployment pipelines; infrastructure as code (IaC), automated monitoring, feedback loops

Role of DevOps in MedTech: e.g. reliability, scalability, security, regulatory compliance, operational efficiency

Industry-specific adaptations: e.g. clinical workflows, healthcare interoperability, data integrity, real-time monitoring.

DevOps tools and technologies:

CI/CD pipelines: e.g. Jenkins, GitLab CI/CD, CircleCI, Azure DevOps, Travis CI

Configuration management: e.g. Ansible, Puppet, Chef, Terraform, Kubernetes

Version control and collaboration: e.g. Git, GitHub, GitLab, Bitbucket, branching strategies

Infrastructure as Code (IaC): e.g. Terraform, CloudFormation, Helm charts, immutable infrastructure, scripting, deployment automation, configuration management, Terraform, Ansible

Monitoring and logging: e.g. Prometheus, Grafana, ELK Stack, Splunk, Dynatrace, APM tools

Cloud platforms and deployment models: e.g. AWS, Azure, Google Cloud, hybrid-cloud, on-premises.

MedTech-specific DevOps practices:

Medical software development: e.g. mobile health apps, diagnostic tools, AI-driven medical analysis

Embedded systems and IoT: e.g. wearable devices, patient monitoring, remote healthcare, edge computing

Healthcare system interoperability: e.g. HL7, FHIR, DICOM, API security, data integration

Failure management and disaster recovery e.g. redundancy, failover, high availability, rollback mechanisms.

LO2 **Explain the benefits and challenges of applying a DevOps methodology to organisations within the MedTech sector**

Benefits of DevOps in MedTech:

Faster time-to-market: e.g. automated testing, CI/CD, reduced deployment cycles, rapid iteration, accelerated releases, competitive advantage

Enhanced software quality: e.g. continuous testing, automated validation, reduced defects, consistent environments, real-world feedback

Scalability and performance: e.g. cloud-native applications, auto-scaling, performance monitoring

Operational efficiency: e.g. infrastructure automation, optimised resource utilisation, reduced downtime, reduced manual interventions, optimised workflows

Cross-disciplinary collaboration: e.g. developers, IT operations, security teams, regulatory bodies, clinicians; improved collaboration (e.g. team synergy, shared goals, cross-functional interaction).

Challenges and limitations:

Complexity of implementation: e.g. toolchain integration, process changes, skill requirements

Cultural resistance and skill gaps: e.g. adoption challenges (e.g. organisational inertia, resistance to change, stakeholder buy-in), need for specialised DevOps expertise, training requirements, team integration resistance, working practice changes

Regulatory constraints: e.g. MDR/IVDR, FDA approvals, ISO 13485, software validation, post-market surveillance, compliance adherence, documentation requirements, validation processes

Security and privacy risks: e.g. protected health information (PHI), compliance risks, API security, vulnerability management, data protection, secure deployments

Integration with legacy systems: e.g. monolithic applications, compatibility issues, outdated technologies

Cost implications: e.g. cloud infrastructure costs, toolchain investment, compliance overhead, training costs, infrastructure (e.g. hardware, software, networking).

LO3 **Analyse the regulatory compliance, security and privacy practices in MedTech DevOps**

Regulatory frameworks and compliance standards:

MDR (Medical Device Regulation): e.g. device classification, post-market surveillance, clinical validation

IVDR (In Vitro Diagnostic Regulation): laboratory testing compliance, risk assessment, documentation

Compliance standards: e.g. ISO 13485 (quality management systems), ISO 14971 (medical device risk management), IEC 62304 (medical device software life cycle, software safety classification)

HIPAA and GDPR: e.g. data protection, patient privacy, consent management, cross-border data processing

FDA software and cybersecurity guidelines: e.g. secure software development, validation, real-time auditing, documentation, pre-market submissions

Compliance audits: e.g. periodic reviews, certification processes, corrective actions.

Cybersecurity risks in MedTech DevOps:

Threat vectors: e.g. ransomware, insider threats, data breaches, supply chain attacks

Vulnerabilities: e.g. API security flaws, weak authentication, misconfigured cloud storage

Medical device cybersecurity: e.g. remote attacks, firmware vulnerabilities, device hijacking

Secure coding and risk mitigation: e.g. code reviews, security patches, vulnerability scanning

Access control and identity management: e.g. identity theft, social engineering, phishing, access control breach.

Security and privacy best practices:

Secure coding practices: e.g. code reviews, secure development life cycle, vulnerability scanning

Vulnerability management: e.g. patch management, CVE insights, mitigation strategies

Penetration testing: ethical hacking, security assessments, exploit discovery

DevSecOps integration: e.g. automated security testing, secure software development life cycle (SDLC)

Patient confidentiality: e.g. consent management, anonymisation, secure storage

Data encryption and masking: e.g. end-to-end encryption, tokenisation, anonymisation techniques, data masking; access controls (e.g. role-based access, least privilege principle, identity management, multi-factor authentication (MFA), role-based access control (RBAC))

Data anonymisation: e.g. pseudonymisation techniques, data minimisation, compliance

Incident response and recovery: e.g. threat detection containment, recovery logging, forensic analysis, breach notification, post-incident review, lessons learned

Continuous security monitoring: e.g. SIEM tools, anomaly detection, audit logs.

LO4 **Design a DevOps methodology for an identified scenario within the MedTech sector**

Scenario selection and planning:

Use case identification: e.g. cloud-based health applications, AI-powered diagnostics, remote patient monitoring

Project goals: e.g. objectives, metrics, success factors, risk log, constraints, budget, initial timelines

Stakeholder analysis: e.g. developers, clinicians, regulatory teams, cybersecurity experts; requirements (e.g. user stories, acceptance criteria, prioritisation)

Needs analysis: e.g. requirements gathering, including scalability, security, compliance, patient safety; stakeholder engagement, project scope.

Designing the DevOps workflow:

CI/CD pipeline design: e.g. automation including build, test, deployment; blue-green deployments

Testing and validation: e.g. unit testing, integration testing, user acceptance testing (UAT)

Infrastructure automation: e.g. IaC templates, containerisation, orchestration strategies

Security integration: e.g. static/dynamic code analysis, security policies, compliance scans

Data security and compliance: e.g. privacy-preserving analytics, access control mechanisms, audit trails, documentation, regulatory adherence

Deployment and monitoring strategy: e.g. observability tools, real-time health checks.

Implementation planning:

Task breakdown: e.g. milestones, deliverables, resource planning

Resource allocation: e.g. team roles, responsibilities, tools, budgets

Timeline and milestones: e.g. project schedule, key dates, progress tracking

Monitoring and evaluation: e.g. performance metrics, feedback loops, continuous improvement.

Measuring DevOps success:

Key performance indicators (KPIs): e.g. deployment frequency, lead time for changes, failure rates

Security metrics: e.g. incident response time, vulnerability detection rate, compliance audit scores

Operational metrics: e.g. system uptime, cost optimisation, performance benchmarks.

Feedback metrics: stakeholders, surveys, action plan, issue register.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explore the fundamental principles, tools and practices of DevOps in the MedTech industry</td><td rowspan="5">LO1 and LO2
D1 Critically evaluate, using a range of real-world case studies, the effectiveness of applying DevOps principles, tools and practices to organisations within the MedTech industry, considering challenges and benefits.</td></tr>
<tr><td>P1 Explore, using a range of real-world case studies, the core concepts of DevOps as used in the MedTech sector.
P2 Review, using a range of real-world case studies, the different DevOps tools and technologies and their application to MedTech-specific practices.</td><td>M1 Analyse, using a range of real-world case studies, the principles, tools and practices of DevOps in the MedTech industry.</td></tr>
<tr><td colspan="2">LO2 Explain the benefits and challenges of applying a DevOps methodology to organisations within the MedTech sector</td></tr>
<tr><td>P3 Explain, using a range of real-world case studies, the benefits of applying a DevOps methodology to organisations within the MedTech sector.
P4 Discuss, using a range of real-world case studies, the challenges of applying a DevOps methodology to organisations within the MedTech sector.</td><td>M2 Analyse, using a range of real-world case studies, the benefits and challenges of applying a DevOps methodology to organisations within the MedTech sector.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Analyse the regulatory compliance, security and privacy practices in MedTech DevOps		
P5 Review, using a range of real-world case studies, regulatory frameworks and compliance standards used by DevOps in the MedTech sector. **P6** Discuss, using a range of real-world scenarios, the cybersecurity risks and associated best practices implemented by DevOps in the MedTech sector.	**M3** Analyse, using a range of real-world case studies, the regulatory compliance, security and privacy practices in MedTech DevOps.	**D2** Evaluate, using a range of real-world scenarios, the effectiveness of regulatory compliance, security and privacy practices in MedTech DevOps.
LO4 Design a DevOps methodology for an identified scenario within the MedTech sector		
P7 Design a DevOps methodology for an identified scenario within the MedTech sector, considering the workflow, implementation and measurements of success. **P8** Review the developed DevOps methodology with a variety of key stakeholders to identify a range of strengths, weaknesses and areas for improvement.	**M4** Justify, using the contents of the stakeholder review, the choices made in the development of the DevOps methodology for an identified MedTech scenario.	**D3** Critically evaluate the effectiveness of the DevOps methodology in how well it aligns with the identified objectives of the MedTech scenario, making recommendations for any future actions.

Recommended Resources

Textbooks

Alt, R., Auth, G. and Kögler, C. (2021) *Continuous Innovation with DevOps: IT Management in the Age of Digitalization and Software-defined Business*. Cham: Springer.

Coupland, M. (2021) *DevOps Adoption Strategies: Principles, Processes, Tools, and Trends: Embracing DevOps Through Effective Culture, People, and Processes*. Birmingham: Packt Publishing Ltd.

Davis, J. and Daniels, R. (2016) *Effective DevOps: Building a Culture of Collaboration, Affinity, and Tooling at Scale*. Sebastopol CA: O'Reilly Media, Inc.

Kim, G., Humble, J., Debois, P., Willis, J. and Forsgren, N. (2021) *The DevOps Handbook: How to Create World-Class Agility, Reliability, & Security in Technology Organizations*. 2nd Ed. Portland: IT Revolution Press.

Knight, J. and Swenson, N. (2022) *The DevOps Career Handbook: The ultimate guide to pursuing a successful career in DevOps*. Birmingham: Packt Publishing Ltd.

Krief, M. (2022) *Learning DevOps: A comprehensive guide to accelerating DevOps culture adoption with Terraform*, Azure DevOps, Kubernetes, and Jenkins. Birmingham: Packt Publishing Ltd.

Mulder, J. and Mulder, H. (2022) *Transforming Healthcare with DevOps: A Practical DevOps4Care Guide to Embracing the Complexity of Digital Transformation*. Birmingham: Packt Publishing Ltd.

Websites

www://about.gitlab.com/blog/2022/02/11/4-must-know-devops-principles/	4 Must-know DevOps principles (Blog)
www.atlassian.com/devops/devops-tools	DevOps Tools (Article)
www://aws.amazon.com/devops/what-is-devops/	What is DevOps? (Article)
www.bunnyshell.com/blog/challenges-of-devops/	16 Challenges of DevOps in 2021 – From Adoption to Implementation to Scaling (Blog)
www.kcl.ac.uk/policy-institute/assets/trusted-autonomous-systems-in-healthcare.pdf	Trusted autonomous systems in healthcare (Review)

www://kms-healthcare.com/blog/devops-in-healthcare	What is DevOps in Healthcare? A Strategic Approach (Article)
www.knowledgehut.com/blog/devops/devops-methodologies	DevOps Methodologies: Understanding the Practices & Principles (Blog)
www://spacelift.io/blog/devops-tools	73 Most Useful DevOps Tools to Use in 2025 (Blog)
www.techtarget.com/searchitoperations/definition/DevOps	What is DevOps? Meaning, methodology and guide (Article)
www://ventionteams.com/blog/devops-in-healthcare	DevOps in healthcare: a complete guide (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 501: Data Management and Cybersecurity

Unit 502: Computer Systems Validation

Unit 505: Manufacturing Processes

Unit 515: Advanced Manufacturing.

Unit 508: Professional Development

Unit code: **T/651/7114**

Unit level: **5**

Credit value: **15**

Introduction

The MedTech industry is characterised by rapid advancements and continuous innovation, necessitating a commitment to lifelong learning and professional growth.

Professional practice is essential in ensuring that MedTech products and services are delivered effectively and efficiently. The sector demands high degrees of professionalism and adherence to regulatory standards to ensure delivery of quality products and services to both clinicians and patients. This unit is designed to give students the core principles of professionalism required in these fields. It prepares them to navigate their careers, where decision-making, critical thinking and reflective practice are fundamental to daily operations.

The purpose of this unit is to give students a comprehensive foundation in the essential professional practices necessary for success in the MedTech sector. Students will engage with a range of frameworks, reflective practices, critical reasoning and the importance of continuing professional development (CPD). These components help students develop a clear understanding of what it means to act professionally in high-stakes environments. Through practical applications of theoretical knowledge, students will analyse and improve their own professional conduct, ensuring they meet the rigorous standards expected in their respective fields. Students will also explore the process of reflection, addressing its challenges, and understanding how reflective practice can support personal and professional growth.

This unit covers a variety of key topics critical for advancing professional practices in the MedTech sector. Students will engage in reflective practice to evaluate their actions and decisions, and explore how critical reasoning can be applied to problem solving in real-world scenarios. Additionally, the importance of CPD is emphasised, helping students understand how ongoing learning plays a vital role in career progression and higher-level learning within the MedTech sector. The unit builds to a range of practical components, where students will deliver a workshop on an identified topic to a target audience, that allows students to demonstrate a range of professional behaviours. Students will gather and review feedback on the workshop to identify a range of professional development objectives and will apply their knowledge obtained in this unit to develop and evaluate their own CPD plan.

On completion of this unit, students will have developed essential skills such as reflective practice, critical reasoning, applying professional behaviours, problem solving and the ability to create and review professional development plans. They will also gain an understanding of the need for CPD and its significance in maintaining and enhancing skills throughout their careers. These skills will be applicable to a wide range of roles in the MedTech sector, including Systems Engineer, Clinical Applications Specialist, Quality Assurance Manager, Technical Support Specialist, Application Support Analyst and Helpdesk Technician.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Examine the process of reflection and its application and challenges in professional practice

LO2 Discuss the need for continuing professional development (CPD) and its role within the MedTech sector

LO3 Deliver a workshop on an identified MedTech topic that shows professionalism

LO4 Design a CPD plan for a range of identified objectives based on workshop feedback.

Essential Content

LO1 Examine the process of reflection and its application and challenges in professional practice

Reflective practice:

What reflection is, what reflective practice entails, the importance of improving professional performance, improving personal growth in the MedTech sector.

Theories and models of reflection:

Key theories and models of reflection, including Kolb's experiential learning cycle, description, stages, importance and improvement using the theoretical method

Gibbs's reflective cycle, description, stages, importance and improvement using the theoretical method

Schön's reflective practice (1983), description, stages, importance and improvement using the theoretical method.

Application of reflective practice:

Self-assessment tools, SWOT analysis (strengths, weaknesses, opportunities, threats), reflective logs, SMART goals, key performance indicators (KPIs), reflective journals

Incorporating reflection into professional practice, e.g. daily routines, routine reflection exercises, reflection after critical incidents, routine tasks, implantation of structured reflection periods, reflection sessions as teams or individualised.

Challenges in reflective practice:

Barriers to reflection: e.g. obstacles, time constraints, lack of training, organisational culture

Strategies to overcome barriers: e.g. time-management techniques, specific time for reflection, training programmes, focus of reflective skills, creating a supportive organisational culture, setting objectives, peer review, evidence-based practice and framework, balancing emotional and factual insight

Culture of the MedTech sector: e.g. growth mindset, acceptance of failure, iterative learning, embracing innovative approaches, fostering resilience, continuous improvement

Workplace function: e.g. professional expectations, understanding corporate culture, adapting to MedTech industry standards, workplace dynamics, collaboration within multi-disciplinary teams, role clarity

Mental health: e.g. stress management, work–life balance, support systems, mental health awareness, resilience-building strategies, reducing burnout, promoting a healthy workplace environment.

LO2 Discuss the need for continuing professional development (CPD) and its role within the MedTech sector

Continuing professional development (CPD):

Definitions and purpose of professional development, what CPD means in MedTech, importance of maintaining professional development practice in a rapidly changing field

Benefits of CPD, including keeping up to date with industry advancements, enhancing professional competencies, job satisfaction, career progression opportunities, maintaining a competitive edge in the industry

CPD and creativity: quantification difficulty, subjective nature, innovative problem solving, non-linear thinking, balancing regulatory compliance with creative solutions.

CPD activities and opportunities:

Formal learning: e.g. accredited courses, workshops, seminars, online training, training programmes, MedTech-certificated courses

Informal learning: e.g. self-directed learning, peer group learning, on-the-job training and experiences

The role and importance of organisations such as the Regulatory Affairs Professionals Society (RAPS), International Society for Pharmaceutical Engineering (ISPE) and the Medical Device Innovation Consortium (MDIC)

Online platforms: e.g. digital learning platforms, MedTech-specific courses, LinkedIn learning and networking for MedTech professionals.

Planning and recording CPD:

CPD planning, including the principles of structured CPD linked to professional development goals and organisational requirements

CPD records and logs: e.g. detailed logs, records of activities, maintaining accurate progress, certification

CPD impacts: e.g. evaluating impacts, metrics and methods of measuring impacts, measuring impacts on development, measuring impacts on service delivery.

Role of CPD in career advancement:

Career progression: achieving higher-level qualifications, qualifying for advanced job positions in the MedTech industry, linking CPD qualifications to job roles, the relationship between ongoing CPD activity and formal MedTech regulations (e.g. ISO 13485, ISO 14971 certification, ISO 14644 standards for cleanroom services, and MDR training)

MedTech sector examples: genomics, medical devices, diagnostic imaging, in vitro diagnostics, digital health technologies, biotechnology, orthopaedics.

LO3 **Deliver a workshop on an identified MedTech topic that shows professionalism**

Workshop planning:

Defining objectives: e.g. workshop aims, SMART goals (specific, measurable, achievable, relevant, time-bound), intended audience, audience outcomes, align workshop content with objectives

Content selection and structure: e.g. identify topics, identify content sections, confirm topics align with objectives, balance of theory, practice and discussion

Workshop plan: e.g. registration, introduction, activities and exercises, including number, format (e.g. role play, team-based, seminar, discussion), sequence, summation, differentiation (e.g. by objective, by outcome, by skill level, by job role, by content), assessment opportunities, contingency planning, risk assessments, health and safety requirements (e.g. venue, individual medical needs), feedback opportunities, data gathering, aligning activities with objectives and workshop aims

Resources: e.g. resource formats (e.g. presentation, booklets, handouts, folders, multimedia, music, video), physical activity requirements (e.g. pens, paper, drawing materials, arts and craft, equipment), feedback (e.g. quiz, survey, questionnaire); quality of resources (e.g. clear, concise, engaging, easy to understand, accessible, differentiated)

Organising logistics: e.g. workshop format (e.g. physical, virtual, hybrid), venue identification or virtual platform setup, eating arrangements, technology needs, accessibility considerations, time, date and participant availability

Professionalism: personal appearance, vocal tone and use of language, scene setting, behaviour expectations (e.g. mobile phone use, background chat, late arrivals), quality of resources, depth of subject knowledge, quality of activities, maximising audience benefits (e.g. differentiation, assessment opportunities, adjusting workshop to meet audience requirements), dealing with questions.

Workshop delivery:

Introduction and setting expectations: e.g. workshop purpose and objectives, welcoming, inclusive atmosphere, agenda overview and expected outcomes

Content delivery and activities: e.g. alternation between presentations and activities, activities linked to objectives (e.g. group work, problem solving), encouragement of active participation, maintaining engagement (e.g. visual aids, questions, peer interaction, monitoring of engagement and pacing adjustments, positive reinforcement and validation of contributions, continuous assessment)

Addressing questions and clarifying points: e.g. safe space for questions, additional examples for challenging topics, stretch and challenge activities, context for complex points.

Gathering feedback:

Feedback collection: e.g. surveys, forms, informal discussions, quantitative (e.g. letter grade, star system, marks out of), qualitative (e.g. comments), data, focus on content, delivery and engagement

Reflecting on workshop success: e.g. comparison of objectives with outcomes, participant engagement levels, clarity of delivery, levels of professionalism, self-reflection on facilitation style

Planning for improvement: e.g. feedback-based adjustments, content refinement and activity optimisation for future sessions, new strategies for enhanced engagement and relevance.

LO4 **Design a CPD plan for a range of identified objectives based on workshop feedback**

Analysing feedback:

Data categorisation: e.g. content delivery, engagement strategies, workshop structure, participant outcomes

Data analysis tools: spreadsheets, charts, e.g. Venn diagram, pie charts, bar charts, scatter charts, statistical analysis; analysis of feedback data, arrival at conclusions

Key feedback themes: e.g. patterns, common points, standout comments.

Quantitative metrics: e.g. scores, ratings

Qualitative insights: e.g. participant comments highlighting strengths, memorable activities, engaging methods.

Concept of CPD development:

Definition and significance; importance of ongoing personal and professional development, maintaining and improving skill sets.

CPD plan:

Breakdown of key components, including SMART goals, resource identification (e.g. determine tools, support and resources needed towards set goals), timelines (e.g. realistic timelines towards objectives), evaluation methods (e.g. criteria for assessing progress and measuring success).

Designing a CPD plan:

Self-assessment tools, including use of various techniques: e.g. Myers–Briggs, career inventories, skill assessment

Setting development goals: forming clear, actionable and personalised goals from self-assessed outcomes

Action planning: specific steps, resources, supportive structures, identifiable goals, key performance indicators, measurement and recording activities.

Review of CPD plan:

Monitoring progress, review of techniques and tools, tracking progress, progress diaries, periodic reviews, feedback sessions

Adapting development plans; adjusting strategic plans based on needs, feedback and challenges

Reflection: e.g. reflection on achievements, identifying areas for improvement, preparing future developments, preparing skills for industry (e.g. communication, IT skills, time management, working with others, effective leadership skills, problem solving).

Importance of feedback:

Using feedback in constructive methods, including stakeholders, supervisors, peers, mentors.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Examine the process of reflection and its application and challenges in professional practice</td><td rowspan="2">D1 Evaluate the impact that reflective practice has on professional performance in the MedTech sector.</td></tr>
<tr><td>P1 Explain the concept of reflective practice and its significance in the MedTech sector.

P2 Discuss how reflective practice can be applied in professional settings within the MedTech sector.</td><td>M1 Assess the effectiveness of reflective practice in improving professional performance.</td></tr>
<tr><td colspan="2">LO2 Discuss the need for continuing professional development (CPD) and its role within the MedTech sector</td><td rowspan="2">D2 Evaluate the effectiveness of an identified CPD programme within a defined MedTech sector.</td></tr>
<tr><td>P3 Explain the concept and need for CPD in the MedTech sector.

P4 Discuss the role of a range of CPD opportunities in the MedTech sector.</td><td>M2 Analyse the benefits and limitations of an identified CPD programme within the MedTech sector.</td></tr>
<tr><td colspan="2">LO3 Deliver a workshop on an identified MedTech topic that shows professionalism</td><td rowspan="4">LO3 and LO4

D3 Evaluate the role of CPD in developing professionalism within the identified MedTech sector.</td></tr>
<tr><td>P5 Plan a workshop session for an identified MedTech topic.

P6 Deliver a workshop on an identified MedTech topic that shows professionalism and gather appropriate feedback.</td><td>M3 Deliver an effective, professional workshop on an identified MedTech topic that engages an identified target audience.</td></tr>
<tr><td colspan="2">LO4 Design a CPD plan for a range of identified objectives based on workshop feedback</td></tr>
<tr><td>P7 Analyse the feedback from the workshop delivery to identify a range of professional development objectives.

P8 Design a CPD plan based on the identified objectives and outline strategies for the tracking and evaluation of the CPD.</td><td>M4 Evaluate the effectiveness of the designed CPD plan in helping to meet the identified objectives.</td></tr>
</table>

Recommended Resources

Textbooks

Bassot, B. (2023) *The Reflective Practice Guide: An Interdisciplinary Approach to Critical Reflection*. London: Routledge.

Bolton, G. and Delderfield, R. (2018) *Reflective Practice* 5th Ed. London: Sage Publishing.

Cottrell, S. (2011) *Critical Thinking Skills: Developing Effective Analysis and Argument*. 2nd Ed. London: Palgrave Macmillan.

Ghaye, T. (2011) *Teaching and Learning Through Reflective Practice: A Practical Guide for Positive Action*. 2nd Ed. London: Routledge.

Neugebaur, J. and Evans-Brain, J. (2009) *Making the Most of Your Placement*. 1st Ed. London: Sage Publishing.

Rook, S. (2013) *The Graduate Career Guidebook: Advice for Students and Graduates on Careers Options, Jobs, Volunteering, Applications, Interviews and Self-employment*. New York: Palgrave Macmillan.

Rook, S. (2015) *Work Experience, Placement and Internships*. London: Palgrave Macmillan.

Simpson, S. (2011) *Rediscovering Dewey: A Reflection on Independent Thinking*. London: Wood N Barnes.

Stone, D. and Heen, S. (2014) *Thanks for the Feedback: The Science and Art of Receiving Feedback Well*. New York: Viking.

Websites

www.cipd.org/uk	Chartered Institute of Personnel and Development (CIPD) (General reference)
www://cpduk.co.uk/	Continuing Professional Development (CPD) Standards Office (General reference)
www.gov.uk/career-skills-and-training	Career skills and training (General reference)

Links

This unit links to the following related units:

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 406: Regulatory Compliance

Unit 408: Designing a MedTech Project

Unit 510: Good Practices in MedTech

Unit 514: Emerging Trends and Technologies

Unit 516: Work-Based Experience.

Unit 509: ISO Standard Auditing for Medical Devices

Unit code: Y/651/7115

Unit level: 5

Credit value: 15

Introduction

The medical technology (MedTech) industry is a highly regulated sector where rigorous auditing practices play a vital role in ensuring the quality and safety of medical devices. This unit is designed to provide students with an in-depth understanding of the audit processes within the MedTech industry, emphasising the importance of these audits in maintaining high standards and meeting strict regulatory requirements.

The primary aim of this unit is to educate students on the fundamental principles and applications of audits in the MedTech industry. Using a range of case study analysis and real-world audit checklist investigations, students will gain an in-depth understanding of the audit requirements of the two key MedTech ISO standards ISO 14971 and ISO 13485.

The unit covers a wide range of topics essential to understanding audit requirements in the MedTech sector. Key focus areas include the purpose of audits, the different types of audits, such as internal, external and supplier audits, and the standards and regulatory compliance required for effective auditing practices. Students will explore the requirements for an ISO 14971 and ISO 13485 audit. Finally, students will carry out a practical investigation into a range of real-world checklists that are used by real organisations to help with their ISO standard compliance. This comprehensive, practical approach will help prepare students for the challenges of carrying out an ISO compliance audit in the real world, helping them understand the critical role audits play in the integrity and safety of medical devices.

On successful completion of this unit, students will develop the knowledge and skills required to participate in ISO compliance audits within the MedTech industry, such as audit planning, evidence collection and compliance assessment. They will be able to compare and contrast a range of real-world ISO audio checklists, identifying which ones are suitable for ISO compliance. These skills are directly applicable to various job roles such as Quality Assurance Auditor, Regulatory Affairs Specialist, Compliance Officer and Quality Systems Manager.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explain the purpose of audits in MedTech

LO2 Discuss the different types of audits in MedTech

LO3 Review the audit requirements for ISO standards compliance in MedTech

LO4 Compare and contrast a range of ISO standard compliance audit checklists.

Essential Content

LO1 **Explain the purpose of audits in MedTech**

Purpose and definition of audits:

Independent assessment: objectivity, impartiality, evidence-based, third-party verification

Evidence-based evaluation: audit trail, documentation, record keeping, traceability

Verification of SOPs: workflow analysis, procedure validation, task compliance

Quality system performance: output measurement, benchmarking, continuous monitoring

Process adherence: regulatory alignment, task-specific controls, staff conformance

Organisational accountability: transparency, ethical oversight, decision-making support.

Benefits of auditing:

Product quality: e.g. quality control (e.g. inspection plans, test methods, sampling strategies), quality enhancement (e.g. process improvements, technology upgrades, training programmes), reduced defects (e.g. failure mode and effects analysis (FMEA), root cause analysis (RCA), incident tracking)

Continuous improvement: performance metrics (e.g. key performance indicators (KPIs), benchmarking, continuous monitoring systems), feedback loops, innovation triggers

Risk identification: e.g. vulnerability detection, hazard tracking, corrective and preventive actions (CAPA), risk reduction (e.g. regulatory risks, operational risks, financial risks)

Financial integrity: e.g. accurate financial records, fraud prevention, cost control

Operational efficiency: e.g. workflow optimisation, process streamlining, time saving

Resource allocation: e.g. workforce planning, financial resource management, material resource management

Strategic management insight: e.g. decision support, policy development, leadership oversight

Regulatory compliance support: e.g. ISO, FDA, MHRA adherence, audit readiness

Staff training and development: e.g. skills mapping, learning needs, upskilling initiatives

Assurance for external stakeholders: e.g. investor confidence, patient safety, customer trust, regulatory trust

Management review contribution: e.g. reporting accuracy, issue escalation, follow-up actions

Quality assurance: product quality (e.g. medical device accuracy, safety checks, performance measures), process quality (e.g. standard operating procedures, process validations, workflow efficiencies).

Challenges of auditing:

Audit fatigue: e.g. repetitive scrutiny, disengagement risk, compliance burnout

Resource constraints: staff limitations, time pressures, cost implications, training requirements, technological (e.g. hardware, software, network, audit systems, information systems, data analysis)

Resistance to feedback: e.g. defensive culture, communication breakdown, denial of issues

Non-conformance under-reporting: e.g. hidden gaps, selective disclosure, audit bias

Evidence availability issues: e.g. lost records, incomplete documentation, digital access limits

Cultural barriers: e.g. hierarchical silos, international regulatory divergence, values misalignment

Implementation delays: e.g. follow-up lag, system update backlogs, process inertia

Communication breakdowns: e.g. unclear findings, jargon-heavy reports, stakeholder misalignment

Regulation complexity: diverse standards (e.g. local, international, industry, device-specific), international regulations, regulation updates.

LO2 **Discuss the different types of audits in MedTech**

Internal audits:

Departmental evaluation: unit-based scope, cross-functional input, targeted procedures

Quality manual verification: policy review, version control, compliance matrix

SOP and form review: documentation structure, revision logs, template accuracy

Checklist-based methodology: predefined questions, scoring system, structured process

Organisational self-assessment: in-house audit team, self-reporting, improvement identification

Senior management approval: formal endorsement, audit planning, escalation procedures

Audit scheduling and planning: frequency setting, calendar integration, scope definition, audit policies.

External audits:

Third-party auditors: independent evaluators, audit firms, certification bodies

Certification body inspections: ISO bodies, notified bodies, accreditation audits, audit cycle

Regulatory agency assessments: e.g. MHRA, FDA, EMA, TGA involvement, statutory obligations, inspection checks, regulatory submissions

EU MDR, FDA 21 CFR compliance audits: legislation mapping, labelling checks, traceability

Unannounced audit protocols: surprise visits, real-time documentation, audit preparedness

Evidence documentation: signature logs, digital audit trail, secure archiving

External impartiality requirements: non-affiliated auditors, third-party integrity, independence assurance.

Supplier audits:

Third-party supplier evaluation: quality agreements, vendor selection criteria

Quality system verification: ISO certifications, performance audits, inspection readiness

Product/service compliance: batch conformity, service-level adherence, delivery accuracy

Annual performance review: key metrics tracking, feedback sessions, scorecard analysis, performance reviews

Equipment and consumables assessment: calibration logs, shelf life, packaging standards

SLA monitoring: contractual obligations, lead time targets, deviation handling.

Additional audit types:

Clinical audits: patient outcomes, treatment efficacy, evidence-based practice.

Surveillance audits: periodic follow-ups, ongoing compliance, monitoring frequency

Process audits: production flow, validation, root cause detection

Product audits: design compliance, user acceptance, defect rates

Gap analysis reviews: standard comparison, policy alignment, readiness checks

Pre/post-market audits: life cycle integration, regulatory submission, adverse event review.

LO3 **Review the audit requirements for ISO standards compliance in MedTech**

Fundamentals of ISO 14971 audit requirements:

Risk management plan: e.g. product life cycle, production, post-production information review

Risk analysis: e.g. hazard analysis, device considerations (e.g. materials, design, intended use, other relevant factors)

Risk evaluation, including probability of occurrence, severity of potential harm.

Risk controls: e.g. implementation, mitigation, reduction

Residual risk assessment: e.g. remaining risks, assessment of acceptability

Risk management review: e.g. regular reviews, timescales, frequencies, gap identification and analysis, areas for improvement, corrective actions (e.g. implementation, verification)

Production and post-production information: e.g. collection, review, actions, identify potential issues and risk

Documentation requirements: e.g. risk management file (e.g. risk analysis, evaluation, controls, residual evaluation); risk control implementation and verification; evidence of effectiveness of corrective actions

Auditing process: e.g. gathering evidence, reporting findings, corrective actions, verifying effectiveness.

Fundamentals of ISO 13485 audit requirements:

Documented QMS: e.g. defining policies, objectives, procedures, work instructions

Controlling processes: e.g. control and documentation of product life cycle (e.g. design, development, production, distribution)

Internal audits: e.g. requirements, frequency, QMS assessment, identify areas for improvement

Management reviews: e.g. requirements, frequency, QMS effectiveness assessment, adjustments

Corrective and preventive actions (CAPA): e.g. formal process requirement, address non-conformances, prevent recurrence

Demonstrating compliance: e.g. QMS demonstration, evidence (e.g. documentation, records)

Addressing non-conformities: identification, prompt addressing, effective addressing

Risk management system: implementation, maintenance, purpose (identification, assessment, mitigation)

Documentation and records: e.g. clear and comprehensive documentation, including procedures, records and audit reports

External audits: two-stage registrar audit, external parties, certification requirement.

Auditor competence and independence:

ISO training requirement: e.g. standard familiarity, qualification, course completion

Objectivity and impartiality: e.g. role separation, ethical auditing, conflict of interest avoidance

Cross-department audit restrictions: e.g. independence enforcement, process neutrality

Technical knowledge in MedTech: e.g. device understanding, life cycle familiarity, hazard awareness

Understanding of quality systems: e.g. process maps, QMS components, traceability expectations

Audit methodology proficiency: e.g. questioning techniques, observation recording, scoring

Certification body requirements: e.g. auditor approval, third-party recognition, ongoing CPD.

LO4 **Compare and contrast a range of ISO standard compliance audit checklists**

Checklist development:

SOP-based question generation: e.g. clause alignment, policy tracing, structured logic

Evidence identification: e.g. physical records, digital screenshots, staff testimony

Non-conformance criteria: e.g. compliance criteria, evaluation methods, threshold breaches, incomplete practices, undocumented actions

Risk level indicators: e.g. severity ranking, impact analysis, priority setting

Document reference mapping: e.g. cross-referencing, control numbers, archival sources

Template formatting standards: e.g. standard layout, uniform terminology, audit form usability.

Presentation techniques and soft skills:

Data visualisation: e.g. graphs, charts, diagrams, models, slides, statistical analysis, performance benchmarks

Effective communication: e.g. clarity, conciseness, audience adaptation, technical language audience engagement (e.g. interactive questioning, feedback incorporation, knowledge level adaptation), storytelling approach

Regulatory and compliance language: e.g. accuracy in claims, evidence-based justifications, citation of clinical trials

Soft skills: e.g. public speaking, body language, eye contact, professional demeanour

Equality, diversity and inclusion (EDI) considerations: e.g. listener demographics, ethnic backgrounds, language selection, technological understanding, message suitability, visual representation, engagement strategies, accessibility enhancements.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explain the purpose of audits in MedTech</td><td rowspan="4">LO1 and LO2

D1 Critically evaluate, using a range of real-world case studies, the effectiveness of the roles and purpose of the different types of audits in MedTech.</td></tr>
<tr><td>P1 Explain, using a range of real-world case studies, the purpose of audits in MedTech.

P2 Explain, using a range of real-world case studies, the benefits and challenges of audits in MedTech.</td><td>M1 Justify, using a range of real-world case studies, the purpose of audits in MedTech, considering their benefits and challenges.</td></tr>
<tr><td colspan="2">LO2 Discuss the different types of audits in MedTech</td></tr>
<tr><td>P3 Discuss, using a range of real-world case studies, the roles of internal and external audits in MedTech.

P4 Explore, using a range of real-world case studies, the roles of supplier and additional types of audits in MedTech.</td><td>M2 Justify, using a range of real-world case studies, the roles and purpose of different types of audits in MedTech.</td></tr>
<tr><td colspan="2">LO3 Review the audit requirements for ISO standards compliance in MedTech</td><td rowspan="4">LO3 and LO4

D2 Critically evaluate, using a range of real-world case studies, how an effective audit checklist can help a MedTech organisation comply with an identified ISO standard.</td></tr>
<tr><td>P5 Review, using a range of real-world case studies, the requirements of an ISO 13485 compliance audit.

P6 Review, using a range of real-world case studies, the requirements of an ISO 14971 compliance audit.</td><td>M3 Justify, using a range of real-world case studies, the audit and auditor requirements for ISO standards compliance in MedTech.</td></tr>
<tr><td colspan="2">LO4 Compare and contrast a range of ISO standard compliance audit checklists</td></tr>
<tr><td>P7 Compare and contrast a range of real-world ISO 13485 or ISO 14971 standard compliance audit checklists.

P8 Present the results of your audit checklist comparison to an identified target audience.</td><td>M4 Analyse how well the identified audit checklists help MedTech organisations meet the requirements for ISO standards compliance.</td></tr>
</table>

Recommended Resources

Textbooks

Elahi, B. (2021) *Safety Risk Management for Medical Devices*. 2nd Ed. London: Academic Press.

Juuso, I. (2022) *Developing an ISO 13485-Certified Quality Management System: An Implementation Guide for the Medical-Device Industry*. Boca Raton: CRC Press

Laman, S.A. ed. (2021) *The ASQ Certified Medical Device Auditor Handbook*. 4th Ed. Milwaukee: Quality Press.

Tobin, J.J. and Walsh, G. (2023) *Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices*. Weinheim: John Wiley & Sons.

Websites

www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap	FDA Medical Device Single Audit Program (MDSAP) (Resource)
www.greenlight.guru/blog/supplier-management-medical-device	Greenlight Guru Ultimate Guide to Supplier Management for Medical Device Companies (Article)
health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en	European Commission Guidance – MDCG endorsed documents and other guidance (Resource)
www.iso.org/iso-13485-medical-devices.html	International Organization for Standardization ISO 13485 Medical devices (Resource)
www.meridian-medical.com/free-medical-device-supplier-audit-checklist/	Meridian Medical Device Supplier Audit Checklist (Blog)

www://mhrainspectorate.blog.gov.uk/2020/03/10/gcp-inspections-expectations-and-the-dos-and-donts-for-hosting/	Gov.UK GCP Inspections: Expectations and the dos and don’ts for hosting (Blog)
www.researchgate.net/publication/387482337_Quality_Audits_in_Medical_Device_manufacturing_Best_Practices_and_Challenges	ResearchGate Quality Audits in Medical Device manufacturing: Best Practices and Challenges (Article)
www.rimsys.io/blog/medical-device-audits-preparation-and-responses	Rimsys Medical device audits – preparation and responses (Blog)
www://simplerqms.com/medical-device-audits/	SimplerQMS Medical Device Audits: Overview, and Tips (Blog)
www://sobelconsult.com/medical-device-internal-audit/	Sobel Medical Device Internal Audit: Key Steps and Best Practices (Article)
www://uk.indeed.com/career-advice/career-development/operational-auditing	Indeed What is operational auditing? (Plus types, pros and cons) (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 406: Regulatory Compliance

Unit 501: Data Management and Cybersecurity

Unit 502: Computer Systems Validation

Unit 513: Quality by Design.

Unit 510: Good Practices in MedTech

Unit code: **A/651/7116**

Unit level: **5**

Credit value: **15**

Introduction

In the rapidly evolving landscape of medical technology, maintaining rigorous standards is vital to help ensure the consistency, safety and effectiveness of medical devices. This unit on Good Practices in MedTech has been designed to give students an understanding of the essential guidelines and principles that illustrate examples of good practice in the MedTech industry. This unit will be very useful for students wanting to work in the MedTech industry, equipping them with an understanding of what constitutes current examples of best practice.

The primary aim of this unit is to provide students with a thorough introduction to the best practices for manufacturing, distribution and documentation within the MedTech industry. Using a combination of theory, case study analysis and practical work, students will gain firsthand experience and understanding of the various processes and structures required to deliver regulatory-compliant good practice in MedTech. The unit contains a wide array of topics essential to the successful implementation of good practices in MedTech. Key areas include the importance of Good Manufacturing Practices (GMP) in ensuring product consistency, patient safety and continuous improvement. Students will explore quality management systems, the significance of maintaining a controlled work environment, and the critical role of personal protective equipment (PPE) and employee training. The curriculum also goes into supplier management, good distribution (GDP) and documentation (GDocP) practices, regulatory compliance and risk management. The unit concludes with a practical component, where students will develop an example of regulatory-compliant good practice for a specific MedTech scenario, ensuring they can apply their knowledge and understanding effectively.

On successful completion of this unit, students will have developed a robust set of skills critical for careers in the MedTech sector. These include the ability to apply GMP principles to ensure consistent product quality, implement stringent safety measures to protect patients and users, and develop effective distribution and documentation protocols. These skills are directly linked to job roles such as Quality Assurance Specialist, Regulatory Affairs Manager and Process Improvement Analyst.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explain the importance of good manufacturing practices (GMP) in MedTech

LO2 Discuss a range of good manufacturing practices in MedTech

LO3 Assess the importance of good distribution and documentation practices in MedTech

LO4 Develop a regulatory-compliant good practice protocol for an identified scenario in MedTech.

Essential Content

LO1 **Explain the importance of good manufacturing practices (GMP) in MedTech**

Background:

Medical device functionality: performance consistency, reliability

Patient safety: critical accuracy, diagnostic reliability, treatment efficacy

Diagnostic accuracy: detection precision, monitoring consistency

Treatment provision: therapeutic effectiveness, operational consistency

Manufacturing errors: defect prevention, error mitigation

User error exclusion: design clarity, usage simplification

Impact mitigation: risk reduction, harm avoidance.

Product consistency concepts:

Uniform quality: standardised processes, consistent execution

Reduced variability: quality control measures, process standardisation

Reduced defects: quality assurance, systematic checks

Consistent performance: reliability metrics, validation protocols.

Patient safety concepts:

Functionality assurance: operational stability, performance verification

Harm prevention: safety measures, risk controls

Electric shock prevention: electrical safety standards, insulation integrity

Radiation exposure control: safe emission levels, shielding protocols

Performance parameters: benchmark settings, threshold metrics.

Continuous improvement concepts:

Feedback loop mechanisms: continuous review, iterative improvements

Quality metrics tracking systems: performance monitoring, continuous assessment

Performance benchmark evaluations: standard reviews, improvements identification.

Fundamentals of regulatory compliance:

ISO 13485: quality management system requirements

Clause 7.5: production control, service provision

FDA guidelines: regulatory frameworks, adherence protocols

ISO standards and requirements: international benchmarks, quality criteria

CE marking criteria: compliance verification, European standards

Documentation requirements: record maintenance, audit trails.

Risk management concepts:

Product recall management: e.g. recall protocols, contingency plans

Compliance evidence: e.g. documentation, validation records

ISO 14971 principles: e.g. risk assessment frameworks, hazard evaluations

Hazard analysis methodologies: HAACCP, risk identification, impact analysis

Risk-ranking frameworks: e.g. severity assessment, priority setting

Preventive measures implementation: e.g. risk controls, mitigation strategies

CAPA (Corrective and preventive actions): e.g. action plans, prevention methods, root cause analysis, impact assessment.

LO2 **Discuss a range of good manufacturing practices in MedTech**

Quality management systems (QMS) concepts:

ISO 13485 guidelines: e.g. quality framework, process standards

Documented processes: e.g. standard operating procedures (SOPs), workflows

Production checklists: e.g. detailed task lists, procedural steps

Risk-based approaches: e.g. hazard analysis, risk evaluation.

Work environment concepts:

Cleanliness standards: e.g. sterile conditions, contamination control

Contamination control: e.g. preventive measures, cleanliness protocols

Equipment calibration: e.g. precise measurements, accuracy checks

Maintenance records: e.g. calibration logs, equipment history

Clean room management: e.g. controlled environments, strict standards

Sterile conditions: e.g. hygiene maintenance, contamination avoidance

Management responsibilities: e.g. representative designation, review procedures, quality planning documentation, resource allocation planning

Cleaning validation: e.g. contaminant identification, cleaning protocols, sampling techniques, acceptance criteria.

Personal Protective Equipment (PPE) concepts:

Biological hazard protection: e.g. pathogen barriers, infection control

Chemical hazard protection: e.g. chemical barriers, exposure prevention

Physical hazard protection: e.g. impact resilience, physical barriers

PPE types: e.g. gloves, face masks, gowns, aprons, goggles, shields.

Employee training concepts:

Procedure and expectations knowledge: e.g. training modules, competency checks

Deviation and non-compliance reporting: e.g. reporting systems, compliance tracking

Process improvement suggestions: e.g. feedback mechanisms, innovation channels.

Supplier management theory:

Supplier evaluation criteria: e.g. quality assessments, performance benchmarks

Quality certification requirements: e.g. ISO 9001, compliance certifications

Site visits if necessary: e.g. facility inspections, operational reviews

Goods-in inspection protocols: e.g. incoming quality checks, acceptance criteria.

Change control and configuration management theory:

Change control: e.g. change identification, evaluation, approval procedures, implementation strategies

Configuration management: e.g. baseline establishment, configuration status, audit practices, document management

Tools and technologies: e.g. configuration management tools, data visualisation, technology integration

Challenges: e.g. complex system dynamics, regulatory compliance, resource constraints, resistance to change.

LO3 **Assess the importance of good distribution and documentation practices in MedTech**

Distribution channel practices:

Warehouse management systems: e.g. inventory control, storage protocols

Third-party logistics providers: e.g. 3PL partnerships, logistics solutions

Product traceability methods: e.g. tracking systems, batch identification.

Transportation practices:

Cold chain logistics management: e.g. temperature-controlled environments, preservation methods

Temperature monitoring solutions: e.g. sensors, data loggers

Shipment validation procedures: e.g. validation protocols, delivery checks.

Compliance documentation practices:

Documentation audits: e.g. internal reviews, quality inspections

Electronic records management: e.g. digital records, secure databases

Audit trail maintenance: e.g. record-keeping accuracy, traceability assurance

Data integrity assurance: e.g. secure storage, tamper-proof records

Regulatory submissions handling: e.g. submission protocols, regulatory adherence

Compliance check protocols: e.g. periodic checks, conformity assessments.

Record-keeping practices:

Document retention periods: e.g. archival standards, regulatory timelines

Access control mechanisms: security protocols, restricted access

Archiving protocols and procedures: long-term storage, retrieval systems.

Manufacturing steps documentation:

Standard operating procedures (SOPs): e.g. workflow documentation, procedural guidelines

Work instructions development: e.g. detailed guides, task specifications

Standardised process adherence: e.g. consistent execution, quality assurance

Consistency in product assembly: e.g. uniform methods, standardised steps.

Traceability practices:

Serial/batch number identification: e.g. unique identifiers, tracking records

Sub-assembly tracking: e.g. component traceability, integration documentation

Final product identification: e.g. batch numbers, lot identification, Stock Keeping Unit (SKU).

Quality control practices:

Inspection protocols: detailed examinations, validation steps

Pass/fail documentation: acceptance criteria, test results

Responsible person sign-off: accountability, compliance certification

Evidence of compliance: record keeping, audit trails.

LO4 **Develop a regulatory-compliant good practice protocol for an identified scenario in MedTech**

Scenario identification:

Objectives: e.g. scope, boundaries, requirements, constraints (e.g. technical, financial, skills, regulatory)

Device life cycle stage identification: e.g. design, production, delivery, post-market

Risk assessment: e.g. identification, severity matrix, mitigation, prevention

Stakeholder analysis: e.g. identification (e.g. internal, external), purpose, requirements

Regulatory requirement: e.g. ISO standards, regulatory frameworks (e.g. FDA, MHRA, MDR/IVDR).

Protocol development:

Process design principles: e.g. workflow creation, procedural innovation

Flowchart creation methodologies: e.g. visual aids, step sequences

Step-by-step guideline formulation: e.g. instructional frameworks, detailed steps, checkpoints, milestones, critical control points (CCPs), critical quality points (CQPs).

Compliance checks:

Regulatory review processes: e.g. compliance audits, verification methods

Gap analysis techniques: e.g. process evaluations, deficiency identification, closure plans

Validation procedures: e.g. conformity checks, compliance assurance.

Implementation:

Training plan development: e.g. training modules, capacity building

Resource allocation strategies: e.g. resource mapping, optimisation plans, budget allocation

Timeline establishment: e.g. milestone setting, project scheduling

Monitoring and evaluation protocols: e.g. performance tracking, assessment mechanisms.

Performance metrics:

Internal audit structures: e.g. audit frameworks, compliance checks

Continuous assessment frameworks: e.g. ongoing reviews, improvement loops

Post-market surveillance: e.g. feedback types, data gathering, data analysis.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explain the importance of good manufacturing practices (GMP) in MedTech</td><td rowspan="5">LO1 and LO2

D1 Critically evaluate, using a range of real-world case studies, the effectiveness of a range of good manufacturing practices in MedTech.</td></tr>
<tr><td>P1 Explain, using a range of real-world case studies, the importance of good manufacturing practices in MedTech.

P2 Discuss, using a range of real-world case studies, the importance of regulatory compliance and risk management in good manufacturing practices for MedTech devices.</td><td>M1 Justify, using a range of real-world case studies, the importance of good manufacturing practices in MedTech.</td></tr>
<tr><td colspan="2">LO2 Discuss a range of good manufacturing practices in MedTech</td></tr>
<tr><td>P3 Review, using a range of real-world case studies, the roles of quality management systems in good manufacturing practices.

P4 Discuss, using a range of real-world case studies, a range of good manufacturing practices in MedTech.</td><td>M2 Analyse, using a range of real-world case studies, a range of good manufacturing practices in MedTech.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Assess the importance of good distribution and documentation practices in MedTech		
P5 Assess, using a range of real-world case studies, the importance of good distribution practices in MedTech. **P6** Discuss, using a range of real-world case studies, the importance of good documentation practices in MedTech.	**M3** Justify, using a range of real-world case studies, the importance of good distribution and documentation practices in MedTech.	**D2** Critically evaluate, using a range of real-world case studies, the effectiveness of good distribution and documentation practices in MedTech.
LO4 Develop a regulatory-compliant good practice protocol for an identified scenario in MedTech		
P7 Develop a regulatory-compliant good practice protocol for an identified MedTech scenario. **P8** Present the good practice protocol to a range of relevant stakeholders to gather feedback on how well the audit complies with the relevant regulations.	**M4** Justify the decisions made in the development of the regulatory-compliant good practice protocol, based on your own assessment as well as stakeholder feedback.	**D3** Critically evaluate the effectiveness of the developed good practice protocol in complying with the relevant regulations, identifying strengths and areas for improvement.

Recommended Resources

Textbooks

Bhardwaj, R. (2025) *Economics of the Pharmaceutical and Medical Device Industry: Supply Chain, Trade and Innovation*. New York: Routledge.

Cohen, I.G., Minssen, T., Price II, W.N., Robertson, C. and Shachar, C. eds. (2022) *The Future of Medical Device Regulation: Innovation and Protection*. Cambridge: Cambridge University Press.

Donzé, P.Y. (2022) *Medtech*. Singapore: Springer Singapore.

Elahi B. (2021) *Safety Risk Management for Medical Devices*. 2nd Ed. London: Academic Press.

Juuso, I. (2022) *Developing an ISO 13485-Certified Quality Management System: An Implementation Guide for the Medical-Device Industry*. Baco Raton: CRC Press.

Websites

www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp	FDA Quality System (QS) Regulation/Medical Device Current Good Manufacturing Practices (CGMP) (Resource)
www.greenlight.guru/blog/supplier-management-medical-device	Greenlight Guru Ultimate Guide to Supplier Management for Medical Device Companies (Article)
www.iso.org/standard/59752.html	International Organization for Standardization ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (Resource)

www.iso.org/standard/72704.html	International Organization for Standardization ISO 14971: 2019 Medical devices – Application of risk management to medical devices (Resource)
www.madcapsoftware.com/blog/good-documentation-practices-for-medical-devices/	Madcap Good Documentation Practices for Medical Devices (Blog)
www.pharmout.net/good-documentation-practices-gdocp-gmp/	PharmOut Good Documentation Practices (GDocP) | GMP Basics (Blog)
pmc.ncbi.nlm.nih.gov/articles/PMC7026114/	National Library of Medicine The Essential Principles of Safety and Effectiveness for Medical Devices and the Role of Standards (Review)
www.qualio.com/blog/gmp	Qualio Good Manufacturing Practices (GMP) explained (Blog)
www://safetyculture.com/topics/gmp/gmp-regulations/	SafetyCulture Understanding GMP Regulations (Article)
www.vas.ehealth.fgov.be/webmedseip/en/documents/distribution.pdf	FAHMP Guidance for distributors of medical devices (Guidelines)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 505: Manufacturing Processes

Unit 511: Hardware, Robotics and Autonomous Systems in MedTech

Unit 512: Marketing and Sales Approaches

Unit 513: Quality by Design

Unit 515: Advanced Manufacturing.

Unit 511: Hardware, Robotics and Autonomous Systems in MedTech

Unit code: D/651/7117

Unit level: 5

Credit value: 15

Introduction

The evolution of technology in healthcare has ushered in an era where advanced hardware, robotics and autonomous systems play a significant role in medical applications. This unit aims to give students an overview of the fundamental principles, technologies and applications of this cutting-edge field. As healthcare continues to evolve, understanding the integration, challenges and benefits of these systems is crucial to the improvement of patient outcomes.

The objective of this unit is to provide students with an overall view of the role that hardware, robotics and autonomous systems play within MedTech. This knowledge will be useful for anyone wishing to pursue a career in medical technology, enabling them to understand and appreciate the complexities and challenges within this developing field.

In this unit, students will study a range of topics, including the design and function of medical device hardware, for example sensors, microcontrollers and integrated systems. They will gain an understanding of the mechanics and control systems of medical robots, including surgical and rehabilitation robots. Additionally, the unit will address the rising significance of autonomous systems in healthcare, focusing on AI-driven diagnostics and patient monitoring and will look at the regulatory, ethical and safety considerations of these technologies within a range of MedTech applications.

Upon completing this unit, students will have acquired a wide range of knowledge that will be beneficial for a career in robotics, AI and automation in MedTech. The knowledge gained will prepare them for roles involving the development and operational management of surgical and assistive robots as well as autonomous systems. This knowledge can be used in a range of job roles, including Medical Device Engineer, Robotics Specialist, Autonomous Systems Engineer and Compliance Officer in medical technology firms.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Discuss the principles and components of hardware systems in MedTech applications

LO2 Analyse the role of robotics in a range of MedTech applications

LO3 Explore the use of autonomous systems in a range of MedTech applications

LO4 Evaluate the regulatory, ethical and safety aspects of hardware, robotics and autonomous systems in medical applications.

Essential Content

LO1 Discuss the principles and components of hardware systems in MedTech applications

Fundamental concepts:

Medical device hardware: e.g. definition, categories and applications; role in diagnostics, treatment, monitoring and therapy

Hardware principles: e.g. signal processing, including filtering, amplification, analogue signal dynamics; data acquisition (e.g. sampling rates, digitisation, real-time processing); analogue-to-digital conversion including precision, quantisation, resolution

Electronic components: e.g. circuit design, sensors, microcontrollers, actuators; integrated circuits, transistors, diodes, semiconductors

Embedded systems: e.g. firmware development, real-time processing, power efficiency; hardware–software integration, cybersecurity challenges

Communication protocols: e.g. wired (e.g. USB, RS232, ethernet), wireless (e.g. bluetooth, Wi-fi, Zigbee, LoRa), data transmission standards.

Fundamentals of hardware components in medical devices:

PCB design: e.g. multi-layer boards, high-frequency design, thermal management, manufacturing processes

Processing units: e.g. microcontrollers (e.g. Arduino, STM32, Raspberry Pi); microprocessors (e.g. ARM, Intel, RISC-V); digital signal processors (DSP) for medical imaging; real-time OS (RTOS); communication protocols (e.g. I2C, SPI, UART)

Sensors: biomedical sensors, e.g. EEG, ECG, SpO2, EMG, glucose monitors; environmental sensors (e.g. temperature, humidity, air quality); motion sensors (e.g. accelerometers, gyroscopes, IMUs); other sensors (e.g. pressure, chemical)

Actuators and control systems: e.g. actuators, including linear, rotational, electro-mechanical and micro; stepper motors, piezoelectric actuators; pneumatic and hydraulic systems in prosthetics

Power systems and energy efficiency: e.g. battery technology (e.g. Li-ion, solid-state, supercapacitors); wireless power transfer, energy harvesting, battery management systems (BMS)

Connectivity and IoT integration: e.g. Bluetooth, Wi-fi, NFC, 4G, 5G and 6G in medical devices; cloud computing, edge processing, IoT security.

Theoretical applications of hardware in MedTech:

Diagnostic imaging: e.g. X-ray, MRI, CT, ultrasound

Wearable health technology: e.g. smart watches, fitness bands, biosensors

Implantable medical devices: e.g. pacemakers, neurostimulators, insulin pumps

Drug delivery systems: e.g. infusion pumps, auto-injectors, inhalers

Assistive technology: e.g. prosthetics, mobility aids, brain–machine interfaces.

LO2 **Analyse the role of robotics in a range of MedTech applications**

Introduction to medical robotics theory:

Definition and key characteristics: human–robot collaboration, precision control, automation; adaptability in clinical settings

Evolution and technological advancements: history of medical robotics, advances in AI-assisted robotics

Integration with healthcare systems: interoperability, hospital automation, robotic workflow.

Core robotic technology concepts:

Kinematics and motion planning: e.g. forward and inverse kinematics, path planning, trajectory optimisation, positional accuracy

Dynamics: e.g. force control, motion control, compliance, impedance control

Perception and sensor integration: AI-powered vision, haptic feedback; sensors including tactile sensors, vision sensors, motion sensors, proximity sensors, force–torque sensors

Actuation: e.g. electric motors (e.g. brushed, brushless), pneumatics, hydraulics, shape memory alloys, soft actuators

Control systems and learning algorithms: e.g. PID control, adaptive control, reinforcement learning, robust control, model predictive control; motion planning (e.g. path planning, obstacle avoidance, dynamic replanning, workspace analysis); human–robot interaction, including safe operation, collaborative robots, user interfaces, force feedback.

Role of medical robots:

E.g. surgical robots, minimally invasive robotic-assisted surgery, laparoscopic systems (Da Vinci Surgical System), endoscopic robotic navigation, telesurgery, haptic feedback

Rehabilitation robots: e.g. physical therapy, assistive devices, exoskeletons for motor recovery, prosthetic limb robotics, neural-controlled bionics, motor learning

Diagnostic and imaging robots: e.g. AI-powered ultrasound scanning, robotic-assisted MRI-guided interventions, endoscopy robots, robotic palpation, biopsy procedures

Patient assistance and care robots: e.g. robotic telemedicine platforms, elderly care companion robots.

LO3 **Explore the use of autonomous systems in a range of MedTech applications**

Autonomous systems concepts:

Definition and characteristics: e.g. AI-driven decision-making; real-time processing, system adaptability

Artificial intelligence: e.g. machine learning, deep learning, neural networks, natural language processing

Control systems: e.g. feedback loops, adaptive control, predictive control, fuzzy logic control

Sensor fusion: e.g. integrating multiple sensors, data interpretation, decision-making algorithms, reliability and redundancy

Communication: e.g. IoT (Internet of Things), cloud computing, edge computing, wireless communication protocols

System integration: e.g. machine learning, cloud AI, predictive analytics, human–autonomy interaction in medical workflows.

Key technological theory in autonomous systems:

Artificial intelligence (AI) and machine learning (ML): e.g. neural networks, deep learning, natural language processing

Edge and cloud computing: e.g. AI-powered cloud healthcare solutions, edge AI for real-time diagnostics

Computer vision and image processing: e.g. autonomous decision-making in medical imaging

Human–robot interaction (HRI): e.g. gesture-based control, voice recognition.

Types of autonomous MedTech systems:

Autonomous surgical systems: e.g. AI-assisted robotic surgery, precision automation; image-guided navigation, AI-driven decision-making

Autonomous patient monitoring: AI-powered health tracking, continuous monitoring (e.g. remote health monitoring, wearable devices, telehealth, remote diagnostics)

Autonomous diagnostics: predictive analytics for early disease detection, e.g. AI-driven diagnostic algorithms, automated imaging analysis, predictive diagnostics, decision support systems

Autonomous medication delivery: e.g. insulin pumps, smart pill dispensers, implantable drug delivery systems, closed-loop control

Smart Prosthetics and Assistive Devices: e.g. adaptive-control prosthetics, neuroprosthetics; smart wheelchairs, AI-assisted mobility aids.

Implementation challenges:

Data management: e.g. big data, data privacy, real-time processing, data integrity

Algorithm development: training, validation, performance optimisation, bias mitigation

User acceptance: e.g. usability, trust, transparency, user feedback, changes (e.g. upgrades, new device version, new software versions)

Costs: e.g. hardware (e.g. devices, data storage), infrastructure (e.g. networks, servers), energy consumption, software (e.g. up front, subscription), environmental (e.g. energy costs, carbon footprint, sustainability), maintenance (e.g. technical staff, hardware components, software upgrades, infrastructure, downtime), staff training.

LO4 **Evaluate the regulatory, ethical and safety aspects of hardware, robotics and autonomous systems in medical applications**

Regulatory compliance and standards:

Regulatory authorities: e.g. Medicines and Healthcare products Regulatory Agency (MHRA), UK Health Security Agency (UKHSA), National Institute for Health and Care Excellence (NICE), Care Quality Commission (CQC)

Global Medical Regulations: e.g. UK/EU MDR (Medical Device Regulation, including UK MDR 2002, post-Brexit amendments); EU IVDR (In Vitro Diagnostic Regulation, Diagnostic Devices, Regulatory Requirements, Compliance Standards); FDA guidelines, 21 CFR Part 820, 510(k) submissions, PMA (Pre-Market Approval), Quality System Regulation (QSR), CE marking (conformity assessment, notified bodies), MHRA compliance

Quality and risk management standards: ISO 13485 (Quality Management for Medical Devices)

ISO 14971 (Risk Management in MedTech); IEC 60601 (Electrical Safety in Medical Devices)

Artificial intelligence and robotics legislation: Artificial Intelligence (AI) Regulation, UK AI Strategy, UK Data Ethics Framework, National AI Standards Hub.

Ethical considerations:

Patient safety and informed consent: e.g. transparent AI decision-making, bias in AI and robotics, data privacy, ethical approval

Privacy and data security: e.g. HIPAA, GDPR, secure patient data processing; AI-driven cybersecurity risk management

Equity of access: e.g. healthcare disparities, accessibility, cost implications

Autonomous decision-making: e.g. algorithm bias, accountability, explainability, ethical AI.

Risk and safety management concepts:

Risk management: e.g. risk assessment, hazard analysis, fault tree analysis, FMEA (failure modes and effects analysis)

Clinical validation: e.g. preclinical trials, clinical trials, post-market surveillance, performance metrics

Human factors and usability testing: e.g. accessibility, ergonomics, risk minimisation

Cybersecurity and medical device protection: e.g. secure communication, cyber resilience; data protection, vulnerability management, incident response

Failure mode and effects analysis (FMEA): risk assessment in autonomous systems.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Discuss the principles and components of hardware systems in MedTech applications</td><td rowspan="5">LO1 and LO2

D1 Critically evaluate, using a range of real-world case studies, the effectiveness of hardware systems and robotic technologies in a range of applications in the MedTech sector.</td></tr>
<tr><td>P1 Examine, using a range of real-world case studies, fundamental principles and components of medical devices used in the MedTech sector.

P2 Review, using a range of real-world case studies, the applications of hardware systems in the MedTech industry.</td><td>M1 Analyse, using a range of real-world case studies, the principles and components of hardware systems in the MedTech sector.</td></tr>
<tr><td colspan="2">LO2 Analyse the role of robotics in a range of MedTech applications</td></tr>
<tr><td>P3 Explore, using a range of real-world case studies, fundamental principles and technologies of robotics as used in the MedTech sector.

P4 Discuss, using a range of real-world case studies, the role of robotics in a range of MedTech applications.</td><td>M2 Analyse, using a range of real-world case studies, the application and role of robotic technologies in a range of MedTech applications.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Explore the use of autonomous systems in a range of MedTech applications		
P5 Review, using a range of real-world case studies, the fundamental principles and key technologies of autonomous systems used in the MedTech sector. **P6** Discuss, using a range of real-world scenarios, the use of autonomous systems and the challenges encountered in implementing such systems within the MedTech sector.	**M3** Evaluate, using a range of real-world scenarios, the use of autonomous systems in a range of MedTech applications.	**D2** Justify, using a range of real-world scenarios, the effectiveness of autonomous systems in the MedTech sector, considering the key technologies and implementation challenges.
LO4 Evaluate the regulatory, ethical and safety aspects of hardware, robotics and autonomous systems in medical applications		
P7 Review, using a range of real-world examples, the regulatory and ethical considerations of the use of hardware, robotics and autonomous systems in medical applications. **P8** Discuss, using a range of real-world examples, the risk and safety management considerations of the use of hardware, robotics and autonomous systems in medical applications.	**M4** Analyse, using a range of real-world examples, the regulatory, ethical and safety aspects of hardware, robotics and autonomous systems in medical applications used within the MedTech sector.	**D3** Evaluate, using a range of real-world examples, the regulatory, ethical and safety aspects of hardware, robotics and autonomous systems in medical applications used within the MedTech sector.

Recommended Resources

Textbooks

Donzé, P.Y. (2022) *Medtech*. Singapore: Springer Singapore.

Fosch-Villaronga, E. (2019) *Robots, Healthcare, and the Law: Regulating Automation in Personal Healthcare*. Abingdon: Routledge.

Guo, Y., Dagnino, G. and Yang, G.Z. (2023) *Medical Robotics*. Singapore: Springer Singapore.

Jiang, J., Wu, D., Zhang, Y. and Dai, X. (2024) Medical Robot Technology. Singapore: Springer Nature.

Kramme, R., Hoffmann, K.P. and Pozos, R.S. eds (2011) *Springer Handbook of Medical Technology*. Berlin: Springer Science & Business Media.

Nielsen, B. (2023) *Technology and Medicine: Shaping Modern Healthcare*. Baco Raton: CRC Press.

Pappas, H.P. and Frisch, P.H. eds. (2024) *The Rise of the Intelligent Health System*. Baco Raton: CRC Press.

Seeram, E. and Kanade, V. (2024) *Artificial Intelligence in Medical Imaging Technology: An Introduction*. Cham: Springer Nature.

Websites

builtin.com/robotics/surgical-medical-healthcare-robotics-companies	Medical Robots Transforming Healthcare: 11 Examples (Article)
www.england.nhs.uk/long-read/medical-devices-and-digital-tools/	Medical devices and digital tools (Resource)
www.kcl.ac.uk/policy-institute/assets/trusted-autonomous-systems-in-healthcare.pdf	Trusted autonomous systems in healthcare (Review)
medregs.blog.gov.uk/2024/09/25/an-update-on-our-plans-for-med-tech-regulatory-change/	An update on our plans for MedTech regulatory change (Blog)
www.medtecheurope.org/digital-health/artificial-intelligence/	Artificial Intelligence (Resource)
nepc.raeng.org.uk/media/mmfbmnp0/towards-autonomous-systems-in-healthcare_-jul-2023-update.pdf	Towards autonomous systems in healthcare (Article)

sebokwiki.org/wiki/Healthcare_Systems_Engineering	Healthcare Systems Engineering (Wiki)
www.sidley.com/en/insights/publications/2024/04/regulatory-consideration-for-software-hardware-medical-device	Regulatory Consideration for Software Hardware Medical Device (Article)
standardbots.com/blog/10-ways-robotics-are-being-used-in-healthcare-today	Robotics in Healthcare: Top 10 Use – Cases in 2025 (Blog)
www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices	Medical devices (Resource)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 404: Applied Programming

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 407: Software and UI/UX Design

Unit 501: Data Management and Cybersecurity

Unit 502: Computer Systems Validation

Unit 504: Data Analytics

Unit 507: DevOps Engineering

Unit 513: Quality by Design

Unit 514: Emerging Trends and Technologies.

Unit 512: Marketing and Sales Approaches

Unit code: F/651/7118

Unit level: 5

Credit value: 15

Introduction

In the highly competitive field of medical technology (MedTech), having effective marketing and sales strategies is critical for a business to be successful. This unit is designed to provide students with an in-depth understanding of the relationship between regulatory frameworks and marketing and sales practices within the MedTech industry. By focusing on compliance and data-driven strategies, this unit aims to equip students with the essential knowledge and skills needed to understand the promotion and distribution of medical devices and technologies.

The primary aim of this unit is to provide students with a solid grasp of the regulatory environment governing the marketing and sales of MedTech products, and how this impacts strategic business decisions. Furthermore, the unit emphasises the design and evaluation of comprehensive, data-driven sales and marketing campaigns that align with both business goals and clinical objectives.

The unit encompasses a wide range of areas necessary for a thorough understanding of the marketing and sales of MedTech devices. Core topics include the impact of regulatory requirements on marketing and sales practices, different sales models and customer segmentation strategies, pricing and financial planning, and the development and evaluation of sales and marketing campaigns. The unit also has a practical aspect, where students will design an effective sales and marketing campaign, using data for strategic decision-making, and ensuring alignment with regulatory standards throughout the campaign life cycle. This combination of theory and practical work ensures a complete learning experience, building a comprehensive skill set in MedTech marketing and sales.

On successful completion of this unit, students will have gained a detailed set of skills essential for roles in marketing, sales and regulatory affairs within the MedTech industry. These skills are directly applicable to positions within the Medical Technology sector such as MedTech Marketing Manager, Sales Strategist, Regulatory Affairs Specialist and Product Manager.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Analyse the impact of the regulatory context on the sales and marketing of MedTech devices

LO2 Discuss sales models, customer segmentation, pricing and financial strategies in MedTech

LO3 Design a data-driven MedTech sales and marketing campaign aligned with business and clinical objectives

LO4 Evaluate the effectiveness of the identified sales and marketing campaign in compliance with regulations.

Essential Content

LO1 **Analyse the impact of the regulatory context on the sales and marketing of MedTech devices**

Key marketing terms and concepts:

Marketing: definition, reason for marketing; marketing restrictions (e.g. factual accuracy, risk disclosure, professional endorsements)

Regulatory context: marketing approaches, sales strategies, compliance

Supply chains: design, production, post-market surveillance, complexities

Risk communication: accuracy, clarity, compliance with standards

Regulatory bodies: FDA, EMA, MHRA, TGA

Regulations: MDR, IVDR, promotional limitations.

Regulatory compliance in marketing and sales:

MDR (Medical Device Regulation): e.g. risk-based classification, post-market surveillance, clinical evidence requirements, supply chain responsibility

IVDR (In Vitro Diagnostic Regulation): e.g. diagnostic device compliance, performance evaluation, risk categorisation, regulatory documentation

FDA Regulations: e.g. 510(k) clearance, PMA (Pre-Market Approval), De Novo classification, Unique Device Identifier (UDI)

ISO 13485: e.g. Quality management system (QMS), regulatory documentation, product life cycle risk management, CAPA (corrective and preventive actions)

GDPR and HIPAA: e.g. data privacy, patient consent, secure health data processing, marketing data security

National guidelines: e.g. NHS procurement, reimbursement frameworks, advertising restrictions in different markets.

Impact on sales and marketing:

Regulatory restrictions on marketing claims: e.g. substantiated evidence requirements, clinical efficacy validation, misleading advertising penalties, FDA warning letters

Labelling and packaging compliance: e.g. language requirements, UDI (Unique Device Identification), patient instructions, safety warnings, country-specific labelling standards

Post-market surveillance requirements: e.g. adverse event reporting, field safety corrective actions (FSCA), recalls and withdrawals, market monitoring, user feedback integration

Prohibited marketing practices: e.g. off-label promotion restrictions, false claims regulations, enforcement actions, litigation risks, competitor comparisons restrictions

Healthcare professional engagement regulations: e.g. Sunshine Act (US), transparency reporting, promotional material limitations, physician payment disclosures, CME (Continuing Medical Education) sponsorship rules

Public Relations and Reputation Management: e.g. crisis communication strategies, product recall marketing, corporate responsibility in sales messaging.

Impact on sales strategies:

Market segmentation challenges: e.g. device classification impact, risk-based restrictions, reimbursement system differences, payer acceptance variations, approval pathway dependencies

Pricing and reimbursement regulations: e.g. Medicare and Medicaid coverage, health insurance reimbursement, cost-effectiveness evaluations, NICE (UK) approvals, value-based pricing models

Procurement and tendering compliance: e.g. hospital purchasing guidelines, government contracts, vendor qualification, regulatory risk assessments, competitive bidding requirements

Distribution channel regulations: e.g. authorised distributors, import/export restrictions, third-party compliance audits, cold chain logistics requirements, serialisation mandates

Post-sale compliance obligations: e.g. maintenance requirements, recall management, field service regulations, warranty policies, contract enforcement.

LO2 **Discuss sales models, customer segmentation, pricing and financial strategies in MedTech**

MedTech sales models:

Direct sales: e.g. categories including business-to-business (B2B), business-to-consumer (B2C), business-to-government (B2G), hospital procurement, physician purchases, patient self-purchase, government tendering

Other models: e.g. distributorships, partnerships, e-commerce, subscription models

Distributor-led sales: e.g. regional distributors, independent vendors, exclusive partnership contracts

Hybrid models: e.g. blended direct/distributor strategies, online and offline sales integration

SaaS and service-based models: e.g. software-as-a-service (SaaS), device-as-a-service (DaaS), leasing agreements, service-inclusive pricing

Tender-based sales and public procurement: e.g. NHS procurement, European public tenders, US GPOs (group purchasing organisations).

Customer segmentation and buyer profiles:

Key terms: e.g. demographics, psychographics, healthcare systems

Healthcare professionals (HCPs): e.g. physicians, surgeons, radiologists, primary care providers

Hospital procurement and administrators: e.g. NHS procurement teams, private hospital buyers, equipment standardisation committees

Patients and consumers: e.g. homecare users, chronic disease patients, wellness consumers

Payers and insurance providers: e.g. Medicare, Medicaid, private insurers, reimbursement bodies

Regulatory and institutional buyers: e.g. government agencies, WHO procurement programmes, military healthcare systems.

Pricing strategies and financial planning:

Cost-based pricing: e.g. manufacturing costs, R&D expenses, regulatory compliance investments

Value-based pricing: e.g. patient outcomes, cost savings for healthcare providers, competitive differentiation

Dynamic pricing: e.g. definition, strategies, including group, time, cost-plus, competitor-based, value-based, price skimming, bundle pricing, penetration pricing.

Supply chain management: e.g. logistics, distribution, scalability

Reimbursement models: e.g. NHS tariffs, DRG (Diagnosis-Related Groups), CPT (Current Procedural Terminology) coding, Medicare pricing

Market positioning: e.g. competitive analysis, value proposition, product differentiation

Total cost of ownership (TCO): e.g. consumables, servicing, software updates, training costs

Return on investment (ROI) metrics: e.g. sales conversion rates, lead-to-customer ratio, marketing effectiveness

Financial strategies: e.g. budgeting, forecasting, ROI analysis, financial cycles.

LO3 **Design a data-driven MedTech sales and marketing campaign aligned with business and clinical objectives**

Initial marketing strategy (IMS) and business alignment:

Brand positioning: e.g. competitor analysis, product differentiation, regulatory-approved messaging

Potential marketing channels: e.g. digital advertising, industry conferences, peer-reviewed publications, medical journals

Social media and digital outreach: e.g. LinkedIn, YouTube medical webinars, professional discussion forums

KOL (key opinion leader) engagement: e.g. thought leadership, advisory boards, clinician advocacy within compliance limits.

Market research and data-driven insights:

Customer insights and market feedback: e.g. patient surveys, physician focus groups, healthcare system analysis

Competitive benchmarking: e.g. SWOT analysis, pricing strategy reviews, brand perception audits

CRM (customer relationship management) tools: e.g. Salesforce, HubSpot, lead nurturing, AI-driven customer segmentation

Data analytics and performance metrics: e.g. conversion rates, campaign effectiveness KPIs, sales funnel analysis.

Campaign planning and execution:

Campaign objectives: e.g. alignment with business goals, clinical outcomes, key performance indicator (KPI) identification

Message development: e.g. scientific communication, evidence-based claims.

Product launch strategy: e.g. pre-market awareness, early adopter engagement, clinical education

Integrated marketing communications (IMC): e.g. email campaigns, webinars, medical event sponsorships; actual digital marketing channels (SEO, PPC, social media), traditional marketing, educational events

Budget allocation and ROI forecasting: e.g. marketing spend efficiency, impact measurement, financial modelling

Campaign timeline: e.g. product release, update cycles, response mechanisms

Regulatory compliance checks: e.g. MDR/IVDR advertising approvals, promotional restrictions, post-market monitoring

Cross-department collaboration: e.g. marketing, sales, public relations, technical teams.

LO4 **Evaluate the effectiveness of the identified sales and marketing campaign in compliance with regulations**

Performance metrics and impact analysis:

Plan review: e.g. feasibility, timeline validation, cross-department coordination effectiveness, stakeholder identification

Sales growth and market share assessment: e.g. revenue trends, geographic penetration, repeat purchase rates

Customer engagement metrics: e.g. lead conversion, email response rates, social media traction, event attendance

Competitive market response: e.g. competitive activity monitoring, industry feedback, impact of regulatory updates

Performance metrics: e.g. KPIs, sales targets, conversion rates

Feedback: e.g. customer surveys, focus groups, user testimonials

Continuous improvement: e.g. iterative processes, campaign adjustment, data-driven decisions

Reputational management: e.g. brand integrity, trust building, crisis response.

Regulatory compliance in campaign execution:

Post-market surveillance (PMS) and compliance monitoring: e.g. adverse event tracking, complaint analysis, periodic safety updates

Legal and ethical review of campaigns: e.g. compliance audits, external regulatory inspections, corrective action implementation

Data protection and marketing compliance: e.g. GDPR-compliant email databases, HIPAA-secured patient engagement platforms

Compliance checks: e.g. adherence to regulatory requirements, audit trails.

Implementation monitoring:

e.g. accountability frameworks, milestone tracking, progress reports, regular assessments, compliance verification, inter-agency performance reviews, periodic stakeholder briefings, outcome benchmarking.

Improvement recommendations:

e.g. policy adjustments, upgrades (e.g. resource, device, application, software), training enhancements, procedural updates, technology advancements, expanded stakeholder engagement initiatives, strengthened regulatory body collaboration, improved compliance.

Real-world case studies and continuous improvement:

Successful MedTech marketing strategies: e.g. high-impact campaigns, innovative distribution models, compliance-driven growth

Marketing failures and risk mitigation: e.g. case studies on misleading claims, brand damage recovery, failed product positioning

Post-campaign analysis and optimisation: e.g. data-driven improvements, feedback integration, iterative marketing updates.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Analyse the impact of the regulatory context on the sales and marketing of MedTech devices</td><td rowspan="5">LO1 and LO2

D1 Critically evaluate, using a range of real-world examples, the impact of the regulatory context on the selection of sales models, pricing and financial strategies to identified customer segments in MedTech.</td></tr>
<tr><td>P1 Review, using a range of real-world examples, the key terms and the importance of regulatory compliance in the sales and marketing of MedTech applications.

P2 Discuss, using a range of real-world examples, the impact that regulatory compliance can have on sales and marketing strategies for MedTech products.</td><td>M1 Analyse, using a range of real-world examples, the impact of the regulatory context on the sales and marketing of MedTech devices.</td></tr>
<tr><td colspan="2">LO2 Discuss sales models, customer segmentation, pricing and financial strategies in MedTech</td></tr>
<tr><td>P3 Explain, using a range of real-world examples, the different sales models and customer segments in the MedTech industry.

P4 Review, using a range of real-world examples, the different pricing and financial strategies that are used in the MedTech industry.</td><td>M2 Evaluate the key terms, concepts and categories in MedTech design, manufacture and utilisation.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Design a data-driven MedTech sales and marketing campaign aligned with business and clinical objectives		**LO3 and LO4** **D2** Critically evaluate, using your own analysis and the feedback obtained, the effectiveness of the data-driven MedTech sales and marketing campaign in how well it aligns with business and clinical objectives, as well as complying with regulations, making recommendations for any future actions.
P5 Identify an initial marketing strategy based on market research and data-driven insights that aligns with business and clinical objectives. **P6** Design a data-driven MedTech sales and marketing campaign aligned with business and clinical objectives.	**M3** Analyse the effectiveness of the data-driven MedTech sales and marketing campaign, considering how well it aligns with business and clinical objectives.	
LO4 Evaluate the effectiveness of the identified sales and marketing campaign in compliance with regulations		
P7 Review the developed sales and marketing campaign with a range of key stakeholders and obtain relevant feedback about how well the campaign is compliant with regulations. **P8** Assess the feedback obtained about the developed campaign to identify a range of strengths, weaknesses and areas for improvement.	**M4** Justify, using the feedback obtained, the choices made in the development of a data-driven sales and marketing campaign that complies with regulations, making refinements and improvements where necessary.	

Recommended Resources

Textbooks

Denault, J.F. (2018) *The Handbook of Marketing Strategy for Life Science Companies: Formulating the Roadmap you Need to Navigate the Market*. Baco Raton: CRC Press.

Elton, J. and O'Riordan, A. (2016) *Healthcare Disrupted: Next Generation Business Models and Strategies*. Hoboken: John Wiley & Sons.

Mehta, S.S. (2022) *Commercializing Successful Biomedical Technologies*. 2nd Ed. Cambridge: Cambridge University Press.

Micalo, S. (2022) *Healthtech Innovation: How Entrepreneurs Can Define and Build the Value of Their New Products*. Baco Raton: CRC Press.

Pearson, G. (2019) *Thriving in the Healthcare Market: Strategies from an Industry-Insider for Selling Your Product*. Baco Raton: CRC Press.

Websites

www.abhi.org.uk/code-of-ethical-business-practice/	ABHI Code of Ethical Business Practice (Article)
www.abpi.org.uk/reputation/abpi-2024-code-of-practice/	ABPI ABPI 2025 Code of Practice (Resource)
blog.thecenterforsalesstrategy.com/5-steps-to-a-precise-internal-sales-diagnostic	The Center for Sales Strategy 5 Steps to a Precise Internal Sales Diagnostic (Blog)
www.definitivehc.com/blog/medtech-go-to-market-plan	Developing a comprehensive go-to-market plan for your medical device (Blog)
firstpagesage.com/seo-blog/medtech-marketing-strategy-guide/	Medtech Marketing Strategy: 2025 Guide (Blog)
www.icovy.com/blog/how-to-align-medtech-sales-and-marketing-for-success-in-2023-and-beyond	How to Align Medtech Sales and Marketing for Success in 2023 and Beyond (Blog)

info.idrmedical.com/blog/beyond-traditional-pricing-innovative-pricing-models-in-medtech	Beyond Traditional Pricing: Innovative Pricing Models in MedTech (Blog)
www.medicodigital.co.uk/insights/the-marketers-guide-to-the-eu-mdr-and-advertising-and-promotion-of-medical-devices/	The marketer's guide to the EU MDR and advertising and promotion of medical devices – 2023 update (Article)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 408: Designing a MedTech Project

Unit 503: Managing a MedTech Project

Unit 505: Manufacturing Processes

Unit 506: Understanding User Needs

Unit 510: Good Practices in MedTech

Unit 513: Quality by Design.

Unit 513: Quality by Design (QbD)

Unit code: H/651/7119

Unit level: 5

Credit value: 15

Introduction

The MedTech industry stands at the forefront of innovation, blending advanced technology with medical expertise to help transform healthcare delivery. An important part of this transformation is the design-centric approach known as 'Quality by Design' (QbD). This unit introduces students to the principles and practices of QbD, giving them the knowledge, skills and understanding to be able to design medical devices that are intrinsically safe, efficient, and tailored to meet user needs.

The core aim of this unit is to provide a thorough understanding of QbD in the MedTech sector, emphasising the importance of design thinking in developing high-quality medical products. Through an exploration of real-world case studies and practical activities, students will discover how strategic design choices ensure that MedTech products achieve both regulatory compliance and market success.

This unit covers a broad spectrum of topics essential to the successful implementation of QbD in MedTech design. Students will investigate the purpose and advantages of embedding quality within the design process, review the benefits and challenges of integrating QbD within a business, and explore its application in product design and business environments. Students will explore how QbD integrates structured planning, risk management and transparent design processes to thoroughly understand and focus on user needs. The unit culminates in a practical component, where students will develop a regulatory-compliant QbD methodology specific to a MedTech scenario.

On successful completion of this unit, students will be able to apply QbD principles to MedTech designs, encouraging the ability to design products that excel in quality and regulatory compliance. Students will develop skills in design strategy, risk assessment, regulatory navigation and resource allocation. These competencies are vital for careers in MedTech product design, quality assurance, regulatory affairs and project management.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Explain the purpose of Quality by Design (QbD) in the MedTech sector

LO2 Discuss the business applications of QbD within the MedTech sector

LO3 Review the design applications of QbD in the MedTech sector

LO4 Develop a regulatory-compliant QbD methodology for an identified scenario in the MedTech sector.

Essential Content

LO1 **Explain the purpose of Quality by Design (QbD) in the MedTech sector**

What is Quality by Design?:

User-centric development: quality embedding (e.g. inherent quality, intrinsic value)

Focus on user needs, requirement prioritisation, engagement

Systematic planning: e.g. structured frameworks, step-by-step methods

Strategy development: e.g. goal orientation, long-term vision

Risk management: e.g. identification, prevention, mitigation, audit, evidence

Design process transparency: e.g. clear procedures, oversight frameworks

Monitoring systems: e.g. quality checks, error detection

Resource allocation: e.g. investment tracking, resource utilisation

Sustained effort: e.g. long-term dedication, capacity planning

Specification evolution: e.g. dynamic requirements, iterative refinement, long-term strategies, evolutionary practices

Flexibility in design: e.g. responsive features, adaptive solutions.

Quality assurance concepts:

Regulatory alignment: e.g. market conformity, legal adherence

Process controls: e.g. systematic checks, structured reviews, error prevention, quality assurance

Operational enhancement: e.g. productivity boosts, process improvement, workflow optimisation, speed accelerators, resource management, budget effectiveness

Fit-for-purpose design: e.g. customisation, targeted solutions.

Benefits of QbD:

Manufacturing benefits: e.g. comprehensive user requirement understanding, design clarity, detailed assessment, reduced development time, cost saving, fewer errors, reduced downtime

Product benefits: e.g. enhanced regulatory compliance, proactive safety measures, improved product performance, intuitive usability, user-friendly design, ease of upgrade, component modularisation

Organisational benefits: e.g. operational efficiency, targeted innovation, value addition, competitive advantage, cost savings.

Challenges of QbD:

Complexity: e.g. implementation, extensive planning needs, over-sampling, regulation, auditing, documentation production

Management: e.g. resource allocation, budget constraints, high initial investment, technology integration, workflow modification

Communication: e.g. interdisciplinary collaboration, stakeholder engagement, communication barriers, development team alignment difficulties, unity of vision

Compliance: e.g. non-compliance identification, prevention, mitigation; issues (e.g. diverse regulations, international requirements, compliance complexities, risk management, dynamic market conditions).

LO2 **Discuss the business applications of QbD within the MedTech sector**

Stakeholders and target product profile (TPP):

Identification of end-users: demographic analysis, niche market focusing, specific needs recognition (e.g. tailored solutions, customised offerings)

Pain points analysis: e.g. problem identification, opportunity finding, gap analysis, barrier removal, unmet needs discovery

Purchasing behaviour insights: e.g. cost considerations, value propositions, consumer trends, decision influences

Patient reach expansion: e.g. market enlargement, audience broadening, service optimisation (e.g. process enhancement, throughput maximisation)

Use environments assessment: professional settings (e.g. clinical facility analysis, operational context); home environments (e.g. domestic adaptability, environment suitability).

QbD in business operations:

Performance metrics establishment: functional goals (e.g. objective setting, performance standards); timeframe objectives (e.g. process timing, duration planning)

Business considerations: business viability, financial outlook

Market research: structured interviews (e.g. direct enquiries, participant feedback); distributor insights (e.g. network analysis, market penetration)

Regulatory pathways: approval processes (e.g. certification paths, compliance routes); legal navigation (e.g. regulation mapping, guideline following)

Payment models: reimbursement strategies (e.g. cost recovery optimisation, payment systems); financial planning (e.g. budget forecasting, fiscal management)

Supply chain evaluation: quality of final product, supplier qualification, ongoing monitoring, component traceability, dual sourcing, supplier corrective action.

QbD in post-surveillance operations:

Design changes: formal review (e.g. critical evaluation, structured examination); revalidation (e.g. result assurance, compliance checks)

Third-party involvement: resource considerations (e.g. external input, collaboration potential); market feedback (e.g. adjustment insights, iterative development).

LO3 **Review the design applications of QbD in the MedTech sector**

QbD concepts in product design stages:

Project milestones: e.g. identification, goal setting, progress markers, task delegation, role clarification

Documentation procedures: quality management system (QMS) integration (e.g. quality systems, procedural adherence); standard formats, document consistency

Design inputs: user needs (e.g. feature analysis, specification detailing, functional and non-functional requirements, critical attributes, essential functions); portability considerations (e.g. durability assurance, transport facilitation, mobility planning, space management)

Design outputs: specification documentation (e.g. visual representation, technical imagery); BOM generation (e.g. material listing, component identification); statistical analysis (e.g. samples, methods); software design (e.g. software structuring, use case diagrams, pseudocode, output verification)

Sustainability and environmental considerations: e.g. impact, circular economy, sustainable material selection, end-of-life planning, carbon footprint minimisation.

QbD concepts in design verification and validation:

Testing procedures: e.g. output confirmation (e.g. result validation, requirement checks); element-wise assessment (e.g. piece-by-piece analysis, criterion validation)

Compliance verification: e.g. regulatory adherence (e.g. standard satisfaction, compliance assurance, statistical analysis); quality assurance (e.g. reliability checks, performance validation)

External testing: e.g. independent validation (e.g. outsourced evaluation, objective assessment)

Internal testing: e.g. compliance fulfilment, risk controls, safety standards, documentation

Usability and biocompatibility testing: clinical evaluations (e.g. practical assessments, real-world application); end-user testing (e.g. feedback gathering, satisfaction metrics)

Design history file (DHF): record compilation, data management, archive building; device master record (DMR)/device history record (DHR) management (e.g. document integration, record confidentiality).

Basic statistical procedures:

Key statistics: central tendency (e.g. mean, median, mode); variation or dispersion (e.g. standard deviation, variance, range); data shape (e.g. bell, symmetric, uniform, skewed)

Sampling plans: sample sizes, acceptance criteria; measurable characteristics; sample selection, sample taking

Sampling procedures: e.g. personnel, roles, responsibilities; non-conforming products; applicability to operations (e.g. design verification, design validation, process validation, design input, in-process, final inspection); standards and tools (e.g. ANSI sampling tables).

Statistical implications:

Standard compliance: ISO 13485, ISO 14971 integration

MHRA and FDA requirements: e.g. authority guidelines, compliance protocols; FDA 483: purpose, when issued, why issued, implications, agency enforcement.

LO4 Develop a regulatory-compliant QbD methodology for an identified scenario in the MedTech sector

Scenario planning and product definition:

Device classification: class identification (e.g. categorisation levels, specialisation relevance); usage specification (e.g. operational context, application suitability)

Target population analysis: patient targeting (e.g. demographic focus, audience prioritisation); expectation management (e.g. stakeholder needs, satisfaction metrics)

Clinical need mapping: requirement identification, e.g. need tracing, healthcare gaps

CTQ attributes: e.g. quality prioritisation, critical elements

Submission pathway selection: regulatory alignment (e.g. authority guidance, certification paths); performance requirements (e.g. operational standards, quality benchmarks).

QbD framework elements:

Target product profile (TPP): quality establishment (e.g. critical quality attribute (CQA) definition, critical process parameter (CPP) management); critical material attribute (CMA) identification (e.g. assessment, resource specifics)

Design of experiments (DoE) planning: e.g. experimental setup, analytical modelling.

Failure mode and effects analysis (FMEA): e.g. risk analysis, RPN ranking

Risk management: e.g. control mapping, critical documentation.

Design controls and documentation:

Design verification and validation: protocol establishment (e.g. procedures checks, compliance metrics); review scheduling (e.g. systematic evaluations, project timelines)

Risk management files (ISO 14971): documentation management, risk tracking.

DHF and DMR: e.g. documentation archiving, record confidentiality.

Regulatory compliance alignment:

FDA QbD principles: integration strategy, e.g. principles application, systemic embedding

ISO 13485 and EU MDR: risk management processes, e.g. General Safety and Performance Requirement (GSPR) adherence, regulatory demands

Audit readiness preparation: evidence-based justifications, e.g. design advocacy, compliance fulfilment.

Sampling methodologies:

Acceptance sampling: definition, lot definition ('good', 'bad), decisions, consumer protection

Attribute sampling: e.g. definition, category (e.g. conforming, non-conforming)

Acceptance Quality Limit (AQL): e.g. definition, expression of non-conformance (per cent, per hundred)

Lot Tolerance Percent Defective (LTPD): e.g. definition, purpose

Operating Characteristic (OC) Curve: e.g. definition, probability, discriminatory power

Variable sampling: e.g. definition, parameter, statistics (e.g. size, mean, standard deviation, variance)

Central Limit Theorem: definition, random sample, starting population; sampling distribution (e.g. sample, sample means, distribution of sample means, normal distribution; sample size).

Evaluation and continuous improvement:

Root cause analysis (RCA): integration mechanisms, e.g. process insights, control systems

KPI monitoring and CAPA systems: performance tracking, e.g. indicator establishment, feedback systems.

Audit and post-market clinical follow-up (PMCF) data integration: compliance checks, e.g. review systems, data assimilation

Regulatory change impact assessments: adjustment tracking, e.g. change management, regulatory impacts.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Explain the purpose of Quality by Design (QbD) in the MedTech sector</td><td rowspan="2"></td></tr>
<tr><td>P1 Explain, using a range of real-world case studies, the purpose of QbD in the MedTech sector.

P2 Discuss, using a range of real-world case studies, the benefits and challenges of implementing QbD in the MedTech sector.</td><td>M1 Justify, using a range of real-world case studies, the importance of QbD in the MedTech sector.</td><td>D1 Critically evaluate, using a range of real-world case studies, the effectiveness of QbD in MedTech.</td></tr>
<tr><td colspan="2">LO2 Discuss the business applications of QbD within the MedTech sector</td><td rowspan="4">LO2 and LO3

D2 Critically evaluate, using a range of real-world case studies, the effectiveness of QbD when applied to the business of MedTech.</td></tr>
<tr><td>P3 Discuss, using a range of real-world case studies, how QbD can be used to identify stakeholders and a target product profile (TPP) in the MedTech sector.

P4 Explain, using a range of real-world case studies, how QbD can be used in business operations within the MedTech sector.</td><td>M2 Analyse, using a range of real-world case studies, the application of QbD to a range of business processes within the MedTech sector.</td></tr>
<tr><td colspan="2">LO3 Review the design applications of QbD in the MedTech sector</td></tr>
<tr><td>P5 Review, using a range of real-world case studies, the design applications of QbD in the MedTech sector.

P6 Discuss, using a range of real-world case studies, the statistical procedures and implications of QbD in the MedTech sector.</td><td>M3 Justify, using a range of real-world case studies, the importance of QbD in the design stages of the MedTech sector.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Develop a regulatory-compliant QbD methodology for an identified scenario in the MedTech sector		
P7 Develop a regulatory-compliant QbD methodology for an identified MedTech scenario. **P8** Present the QbD methodology to a range of relevant stakeholders to gather feedback on how well the methodology complies with the relevant regulations.	**M4** Justify the decisions made in the development of the regulatory-compliant QbD methodology, based on your own assessment as well as the stakeholder feedback.	**D3** Critically evaluate the effectiveness of the developed QbD methodology in complying with the relevant regulations, identifying strengths and areas for improvement.

Recommended Resources

Textbooks

Akao, Y. (2024) *Quality Function Deployment: Integrating Customer Requirements into Product Design*. Baco Raton: CRC Press.

Cross, N. (2021) *Engineering Design Methods: Strategies for Product Design*. 5th Ed. Hoboken: John Wiley & Sons.

Elahi, B. (2021) *Safety Risk Management for Medical Devices*. 2nd Ed. London: Academic Press.

Juran, J.M. (2008) *Juran on Quality by Design: The New Steps for Planning Quality into Goods and Services*. New York: Simon and Schuster.

Nielsen, B. (2023) *Technology and Medicine: Shaping Modern Healthcare*. Baco Raton: CRC Press.

Ogrodnik, P.J. (2019) *Medical Device Design: Innovation from Concept to Market*. London: Academic Press.

Saiko, G. (2022) *Bringing a Medical Device to the Market: A Scientist's Perspective.* Singapore: Jenny Stanford Publishing.

Wiklund, M.E. and Wilcox, S.B. (2005) *Designing Usability into Medical Products*. Baco Raton: CRC Press.

Websites

www.fda.gov/media/116573/download	FDA Design Control Guidance for Medical Device Manufacturers (Download)
www.fda.gov/media/160131/download	FDA STATISTICAL TECHNIQUES (Download)
www.mastercontrol.com/gxp-lifeline/quality_product_lifecycle_fda_design_controls_1009/	MasterControl Quality By Design, Total Product Life Cycle, and Seven Ways to Improve Design Controls for an FDA Inspection (Article)

www.meddeviceonline.com/doc/integrating-quality-by-design-qbd-in-0001	MedDevice Online White Paper: Integrating Quality By Design (QbD) In Medical Device Manufacturing (White Paper)
www.mpo-mag.com/enabling-quality-by-design-in-medical-device-manufacturing/	Medical Product Outsourcing Enabling Quality by Design in Medical Device Manufacturing (Review)
www.mt.com/ph/en/home/applications/L1_AutoChem_Applications/L2_PAT/quality-by-design.html	Mettler Toledo Quality by Design (QbD) A Strategic Approach to Defining Critical Process Parameters (Article)
www://qbdworks.com/	QbDWorks Quality by Design for Biotech, Pharmaceutical and Medical Devices (Resource)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 503: Managing a MedTech Project

Unit 505: Manufacturing Processes

Unit 506: Understanding User Needs

Unit 509: ISO Standard Auditing for Medical Devices.

Unit 514: Emerging Trends and Technologies

Unit code: L/651/7120

Unit level: 5

Credit value: 15

Introduction

The MedTech industry is at the forefront of revolutionising healthcare through innovative technologies and trends. This unit explores the application of a range of emerging trends and technologies that are transforming patient care, clinical workflows and the operations of MedTech organisations. This unit is designed to provide students with a deep understanding of how these emerging technologies can be used within the MedTech sector to enhance efficiency, accuracy and overall healthcare outcomes.

The primary aim of this unit is to equip students with an understanding of how the latest technological developments are being applied in MedTech and the legal, ethical and regulatory factors that must be considered. Students will gain insight into the challenges and opportunities that emerging trends and technologies present. The unit content will explore a range of new and emerging trends and technologies, such as artificial intelligence, robotics, 3D printing and the Internet of Medical Things (IoMT). Students will explore the transformative potential of these technologies in diagnostics, patient care and healthcare infrastructure. The unit also addresses essential topics such as Cloud Computing and Big Data, emphasising their impact on healthcare data management, security and interoperability. The unit will go on to discuss the legal, ethical and regulatory considerations of using such new technologies in a patient-centric manner, as well as the challenges and opportunities of integrating new technologies into existing systems and infrastructure. Finally, the unit will culminate with an investigation into how emerging trends and technologies have been used to support MedTech organisations, clinical workflows and patient care.

On successful completion of this unit, students will be able to identify the emerging trends and technologies within the MedTech sector and identify the challenges of implementing such technologies into existing systems. They will be able to navigate the legal and ethical frameworks, analyse complex challenges and identify strategic opportunities. These skills will be invaluable for roles such as Technology Consultant, Regulatory Affairs Specialist and Innovation Manager within the MedTech and broader healthcare industries.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Review a range of emerging trends and technologies applicable to the MedTech sector

LO2 Assess the importance of legal, ethical and regulatory considerations when using emerging trends and technologies in MedTech

LO3 Analyse the challenges and opportunities associated with integrating emerging trends and technologies into MedTech systems and infrastructure

LO4 Investigate the contribution of emerging trends and technologies as a tool to support MedTech organisations, clinical workflows and patient care.

Essential Content

LO1 **Review a range of emerging trends and technologies applicable to the MedTech sector**

Artificial intelligence and machine learning:

Diagnostics: e.g. clinical decision support, medical image analysis, drug discovery

Patient support: e.g. diagnostic tools, personalised medicine, process automation, data management, enhanced patient monitoring, ethical considerations, bias in algorithms.

Robotics and automation:

Advanced robotics in surgery: e.g. minimally invasive procedures, surgical precision, robotic assistants, enhanced outcomes, reduced recovery times, surgical robots, robotic-assisted rehabilitation, exoskeletons, lab automation

High-definition medical imaging: e.g. enhanced visualisation, diagnostic accuracy, imaging techniques, radiology advancements, AI-assisted imaging.

3D printing and bioprinting:

Patient-specific implants, prosthetics, organ-on-chip technology, tissue engineering.

Cloud computing and Big Data:

Processing: e.g. real-time health data processing, electronic health records (EHRs), interoperability, security concerns

Communications: e.g. remote consultations, video conferencing, telehealth services, accessibility, patient convenience

Diagnostics: e.g. health apps, patient education, medication adherence, symptom tracking, mobile diagnostics

Medical apps as devices: e.g. regulatory compliance, functionality, user interface, clinical validation, patient usage

Home health monitoring apps: e.g. chronic disease management, remote monitoring, alerts and notifications, patient empowerment, data sharing with providers

Data mining of clinical datasets: e.g. large datasets, predictive modelling, clinical insights, data analysis, research advancements.

Internet of Medical Things (IoMT):

Connected healthcare ecosystems, telemedicine platforms, IoT-enabled diagnostics

Wearable medical devices: e.g. fitness trackers, health monitoring, biosensors, smart watches, real-time data, patient engagement, remote patient monitoring, neurotechnology

IoT in healthcare: e.g. connected devices, smart sensors, remote monitoring, data integration, patient compliance

VR headsets: e.g. medical training, pain management, rehabilitation, surgical simulations, patient distraction.

LO2 **Assess the importance of legal, ethical and regulatory considerations when using emerging trends and technologies in MedTech**

Legal considerations:

Intellectual property rights: e.g. copyright, trademarks, licensing agreements, trade secrets

Patent protections: e.g. patent infringement, patent filing procedures, patent duration, exclusivity clauses

Data privacy laws: e.g. GDPR (General Data Protection Regulation), HIPAA (Health Insurance Portability and Accountability Act), data encryption, data breach notifications

Compliance requirements: e.g. legal documentation, compliance audits, risk management, compliance training

Liability issues: e.g. product liability, manufacturer responsibility, legal indemnity, consumer protection laws

Contractual obligations: e.g. contracts interpretation, terms and conditions, non-disclosure agreements (NDAs), contract enforcement

Jurisdiction-specific laws: e.g. international regulations, local legal frameworks, jurisdictional legal variations, cross-border legalities.

Ethical considerations:

Patient autonomy: e.g. patient rights, decision-making freedom, personal agency, patient advocacy

Informed consent: e.g. consent forms, clear communication, risk disclosure, voluntary participation

Confidentiality concerns: e.g. data security, information-sharing policies, anonymity, privacy practices

Equity in access: e.g. healthcare disparities, inclusive technologies, global health equality, universal healthcare access

Fair treatment principles: e.g. non-maleficence, beneficence, healthcare justice, ethical treatment

Ethical frameworks: e.g. utilitarianism, deontology, virtue ethics, ethical decision-making models

Bioethics standards: e.g. clinical ethics, research ethics, bioethical principles, bioethical analysis.

Regulatory considerations:

FDA guidelines: e.g. 510(k) clearance, pre-market approval (PMA), investigational device exemptions (IDE), good manufacturing practices (GMP)

CE marking requirements: e.g. European Union regulations, safety standards, conformity assessment, technical documentation

Compliance standards: e.g. International Organization for Standardization (ISO), health technology assessment (HTA), qualified health information technology (QHIT), industry compliance benchmarks

Approval processes: e.g. clinical trial phases, submission protocols, regulatory reviews, post-approval monitoring

Reporting procedures: e.g. adverse event reporting, periodic safety update reports (PSUR), incident reporting systems, vigilance and monitoring

Documentation standards: e.g. regulatory submissions, quality management system (QMS) records, technical files, clinical evaluation reports

Quality assurance protocols: e.g. quality control, risk assessment, standard operating procedures (SOPs), continuous improvement systems.

LO3 **Analyse the challenges and opportunities associated with integrating emerging trends and technologies into MedTech systems and infrastructure**

Technical challenges:

Technical complexity: e.g. system compatibility, integration difficulties, advanced engineering requirements

Data security: e.g. cybersecurity threats, data privacy concerns, secure storage solutions

Scalability: e.g. infrastructure expansion, handling increased data loads, performance optimisation

Interoperability: e.g. cross-platform integration, standardisation issues, device compatibility

Maintenance: e.g. regular updates, system reliability, long-term support needs.

Implementation challenges:

Cost: e.g. high initial investment, ongoing maintenance expenses, budget constraints

Training: e.g. extensive user training, technical support needs, continuous education

User adoption: e.g. resistance to new technologies, user engagement, ease of use

Market acceptance: e.g. consumer trust, industry competition, adoption trends

Early adoption: e.g. waiting for technologies to mature, reputational damage.

Legal and ethical challenges:

Regulatory compliance: e.g. stringent regulations, certification processes, compliance standards

Ethical considerations: e.g. algorithmic bias, transparency issues, fairness in AI

Environmental impact: e.g. energy consumption, e-waste management, eco-friendly practices.

Business opportunities:

Innovation: e.g. driving new solutions, fostering creativity, competitive advantage

Operational efficiency: e.g. streamlining processes, improving workflows, resource optimisation

Collaboration: e.g. working with industry partners, interdisciplinary teamwork, knowledge sharing

Market growth: e.g. expanding market opportunities, new business models, growth potential

Sustainability: e.g. eco-friendly technologies, reduced carbon footprint, sustainable practices.

Patient opportunities:

Patient outcomes: e.g. enhanced treatment accuracy, better patient monitoring, personalised care

Enhanced diagnostics: e.g. improved diagnostic tools, early detection, advanced imaging techniques

Predictive analytics: e.g. AI-driven predictions, preventive care, data-driven insights

Telemedicine: e.g. remote consultations, increased healthcare access, convenient patient care

Personalised medicine: e.g. tailored treatments, genomics, customised healthcare plans

Health monitoring: e.g. wearable devices, continuous monitoring, real-time health data.

LO4 **Investigate the contribution of emerging trends and technologies as a tool to support MedTech organisations, clinical workflows and patient care**

Supporting MedTech organisations:

Operational efficiency: e.g. process automation, resource optimisation, cost reduction, workflow integration

Strategic decision-making: e.g. data analytics, predictive modelling, business intelligence, market trends analysis

Innovation and research: e.g. R&D acceleration, prototyping tools, collaboration platforms, intellectual property management

Regulatory compliance: e.g. compliance tracking, documentation automation, standards adherence, regulatory reporting

Supply chain management: e.g. inventory control, real-time tracking, procurement optimisation, supplier relationship management

Customer engagement: e.g. customer relationship management (CRM) systems, digital marketing tools, customer feedback analysis, support services; scalability (e.g. cloud solutions, modular systems, flexibility, future-readiness).

Supporting clinical workflows:

Electronic health records (EHRs): e.g. patient data digitisation, information sharing, interoperability, access control

Medical imaging: e.g. advanced imaging technologies, visualisation tools, image analysis, diagnostic support

Telemedicine: e.g. remote consultations, virtual follow-ups, telemonitoring, digital prescriptions; laboratory automation (e.g. sample processing automation, result reporting systems, workflow simplification, time efficiency)

Clinical decision support systems (CDSS): e.g. evidence-based guidelines, diagnostic algorithms, decision trees, alert systems

Workflow management: e.g. task automation, scheduling optimisation, coordination tools, communication platforms

Training and education: e.g. simulation tools, e-learning platforms, continued medical education (CME) resources, interactive modules.

Supporting patient care:

Personalised medicine: e.g. genetic profiling, tailored treatments, biomarker analysis, personalised health plans

Remote monitoring: e.g. wearable devices, health sensors, real-time tracking, patient dashboards

Patient engagement: e.g. health apps, self-management tools, interactive portals, health information resources

Disease management: e.g. chronic disease monitoring, treatment adherence tools, symptom tracking, care plan management

Health data analytics: e.g. predictive analytics, outcome measurement, risk stratification, data-driven insights

Patient safety: e.g. error reduction, safety alerts, monitoring systems, medication management; mental health support (e.g. digital therapy tools, telepsychiatry, mood tracking apps, online support groups).

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Review a range of emerging trends and technologies applicable to the MedTech sector</td><td rowspan="5">LO1 and LO2

D1 Evaluate the effectiveness of emerging trends and technologies in a real-world MedTech application, considering the legal, ethical and regulatory implications.</td></tr>
<tr><td>P1 Investigate, using real-world case studies, a range of various emerging technologies that are applicable to the MedTech sector.

P2 Review, using real-world case studies, a range of various emerging trends that are applicable to the MedTech sector.</td><td>M1 Analyse, using a range of real-world case studies, the effectiveness of how emerging trends and technologies have been applied to the MedTech sector.</td></tr>
<tr><td colspan="2">LO2 Assess the importance of legal, ethical and regulatory considerations when using emerging trends and technologies in MedTech</td></tr>
<tr><td>P3 Explain, using a range of real-world case studies, the importance of legal and ethical considerations when using emerging trends and technologies in MedTech.

P4 Discuss, using a range of real-world case studies, the importance of regulatory considerations when using emerging trends and technologies in MedTech.</td><td>M2 Assess, using a range of real-world case studies, the importance of legal, ethical and regulatory considerations when using emerging trends and technologies in MedTech.</td></tr>
</table>

Pass	Merit	Distinction
LO3 Analyse the challenges and opportunities associated with integrating emerging trends and technologies into MedTech systems and infrastructure		**LO3 and LO4** **D2** Justify the contribution of an emerging trend or technology as a tool to support MedTech organisations, clinical workflows and patient care, considering the challenges and opportunities of integrating the trend or technology into the system or infrastructure.
P5 Explore, using a range of real-world case studies, the challenges associated with integrating emerging trends and technologies into MedTech systems and infrastructure. **P6** Explain, using a range of real-world case studies, the opportunities associated with integrating emerging trends and technologies into MedTech systems and infrastructure.	**M3** Analyse, using a range of real-world case studies, the challenges and opportunities associated with integrating emerging trends and technologies into MedTech systems and infrastructure.	
LO4 Investigate the contribution of emerging trends and technologies as a tool to support MedTech organisations, clinical workflows and patient care		
P7 Investigate, using a range of real-world case studies, the contribution of emerging technologies as a tool to support MedTech organisations, clinical workflows and patient care. **P8** Review, using a range of real-world case studies, the contribution of emerging trends as a tool to support MedTech organisations, clinical workflows and patient care.	**M4** Evaluate, using a range of real-world case studies, the contribution of emerging trends and technologies as a tool to support MedTech organisations, clinical workflows and patient care.	

Recommended Resources

Textbooks

Ahmad, N. and Packirisamy, G. eds. (2023) *Emerging Nanotechnologies for Medical Applications*. Amsterdam: Elsevier.

Donzé, P.Y., 2022. *Medtech*. Singapore: Springer Singapore.

Ermak, G. (2015) *Emerging Medical Technologies*. Singapore: World Scientific Publishing Company.

Khang, A. ed. (2023) *AI and IoT-based Technologies for Precision Medicine*. Hershey: IGI Global.

Mehta, S.S. (2022) *Commercializing Successful Biomedical Technologies*. 2nd Ed. Cambridge: Cambridge University Press.

Serrano-Santoyo, A., Kuri-Alonso, I., Durazo-Watanabe, E., and Rojas-Mendizabel, 2021. 'Ethical implications regarding the adoption of emerging digital technologies: an exploratory framework', in *Progress in Ethical Practices of Businesses: A Focus on Behavioral Interactions* (pp.219-239). Cham: Springer.

Stahl, B.C. (2021) *Artificial Intelligence for a Better Future: An Ecosystem Perspective on the Ethics of AI and Emerging Digital Technologies* (p.124). Cham: Springer Nature.

Websites

www.alpha-sense.com/blog/trends/medtech-trends-outlook/	Top Medtech Trends & Outlook For 2024 (Blog)
www.gov.uk/government/publications/medical-technology-strategy/medical-technology-strategy	The role of medical technology in improving health outcomes (Policy Paper)
www.medtecheurope.org/	MedTech Europe (Resource)
www://technologyquotient.freshfields.com/post/102ixnk/10-key-medtech-themes-for-2024	10 Key MedTech Themes for 2024 (Blog)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 501: Data Management and Cybersecurity

Unit 504: Data Analytics

Unit 505: Manufacturing Processes

Unit 507: DevOps Engineering

Unit 513: Quality by Design

Unit 515: Advanced Manufacturing.

Unit 515: Advanced Manufacturing

Unit code: **M/651/7121**

Unit level: **5**

Credit value: **15**

Introduction

The MedTech industry is at the cutting edge of technological advancement, where sophisticated manufacturing processes drive innovation in medical device production. This unit in Advanced Manufacturing is designed to explore these innovative techniques, focusing on how they revolutionise the design and delivery of MedTech devices, from smart materials integration to precision engineering. This unit will give students a glimpse into the latest advancements in medical technology manufacturing, preparing them for a variety of roles in the MedTech sector.

The aim of this unit is to examine a range of advanced manufacturing techniques used in the MedTech industry, emphasising their role in optimising design processes and ensuring product quality. Using a review of real-world case studies, students will discover how these manufacturing methods enhance both product performance and user safety within strict regulatory frameworks.

This unit covers a comprehensive range of topics that are crucial to mastering advanced manufacturing in MedTech. Students will explore smart materials integration and microfabrication technologies, review optimisation strategies for manufacturing processes, and examine a range of advanced manufacturing techniques. They will also evaluate sustainability and compliance considerations. Students will examine a range of process optimisation strategies as well as exploring the range of sustainability considerations necessary for organisations that are manufacturing medical devices. The unit builds towards a practical component where students will build on the unit theory to design their own regulatory-compliant advanced manufacturing process for an identified MedTech scenario.

On successful completion of this unit, students will gain an understanding of how advanced manufacturing techniques can be applied to MedTech product design, enabling them to develop regulatory-compliant advanced manufacturing processes. These competencies are directly linked to employment opportunities in MedTech manufacturing, quality assurance, regulatory affairs and product design.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Review a range of advanced manufacturing techniques in the MedTech sector

LO2 Discuss the optimisation of manufacturing techniques within the MedTech sector

LO3 Explore the sustainability considerations for organisations manufacturing MedTech devices

LO4 Develop a regulatory-compliant advanced manufacturing process for an identified medical device.

Essential Content

LO1 **Review a range of advanced manufacturing techniques in the MedTech sector**

Smart materials integration concepts:

Shape memory alloys: e.g. thermal responsiveness, deformation recovery, mechanical properties

Bioactive materials: e.g. enhanced interaction, cellular response, tissue regeneration

Nanomaterials: e.g. high surface-to-volume ratio, enhanced properties, functionalised surfaces

Examples: e.g. biosensors, artificial muscles, advanced drug delivery systems.

Fundamentals of biocompatible coatings:

Hydrophilic coatings: e.g. improved wettability, tissue compatibility, reduced friction

Antibacterial coatings: e.g. infection resistance, surface sterilisation, prolonged device life

Tissue-compatible interfaces: e.g. integration support, cellular attachment, healing promotion

Examples: heart valves, artificial joints.

Fundamentals of microfabrication and micro electronics mechanical systems (MEMS):

Cleanroom production: e.g. controlled environment, contamination prevention, high purity

Small-scale sensors: e.g. sensor miniaturisation, integrated systems, real-time monitoring

Silicon-based chips: e.g. semiconductor technology, electronic integration, micro-scale functions

Biosensors and accelerometers: e.g. biomonitoring, movement detection, device integration

Examples: bio-monitors (e.g. blood pressure, heart rate, blood glucose); diagnostics (e.g. PCR testing, specimen testing, microfluidics, micropumps); ventilators; activity tracking and motion detection; Minimally Invasive Surgical (MIS) tools (e.g. micro tweezers, biopsy forceps).

Advanced laser techniques – welding:

Purposes: e.g. non-contact joining method, focused thermal energy application, precision seam creation, hermetic seal formation, micro-welding of medical components

Process fundamentals: e.g. focused beam delivery, coherent light source, controlled heat input, melting point precision, mechanical stress reduction

Applications: e.g. implant casing fusion (e.g. pacemakers, neurostimulators); surgical tool subassembly (e.g. forceps, cutters); catheter shaft and connector joining; sensor enclosure welding; battery and electronics housing sealing.

Advanced laser techniques – marking/engraving:

Purposes: e.g. permanent part identification, surface traceability integration

Non-contact, abrasion-resistant labelling, Unique Device Identification (UDI) compliance

Process fundamentals: e.g. thermal surface transformation, optical contrast creation, minimal material removal, direct part marking, no consumable requirements

Applications: e.g. marking of implants and surgical tools, barcoding of reusable devices, serial number etching for diagnostics, inventory coding, label-free product identification, corporate logos.

Advanced laser techniques – surface enhancements:

Purposes: e.g. micro-roughness generation, controlled topography design, surface area increase

Coating adhesion improvement, functional interface creation

Applications: e.g. orthopaedic implants, dental root surfaces, surgical tool grip areas, electrode contact zones, bio-interface customisation, controlled drug delivery patches, textured sensor surfaces.

LO2 **Discuss the optimisation of manufacturing techniques within the MedTech sector**

Optimisation strategies:

Process design: workflow analysis, e.g. process efficiency, layout planning, productivity enhancement

Layout optimisation: e.g. space utilisation, streamlined operations, ergonomic considerations

Resource allocation strategies: e.g. cost minimisation, resource efficiency, capacity planning

In-line inspection systems: e.g. real-time monitoring, defect detection, quality assurance

Real-time monitoring: e.g. system efficiency, continuous feedback, immediate rectification

Statistical process control: e.g. data-driven decision-making, process stability, variance reduction

Lean manufacturing principles: e.g. waste reduction, process optimisation, efficiency improvement

Just-in-time production: e.g. inventory management, demand-driven production, cost control

Waste reduction techniques: e.g. material recovery, energy conservation, environmental impact.

Data-driven manufacturing metrics:

Overall equipment effectiveness (OEE): e.g. efficiency evaluation, operational productivity, performance measurement

Key performance indicators (KPIs): e.g. activity tracking, goal achievement, performance analysis

Mean time between failures (MTBF): e.g. reliability assessment, failure interval, operational stability

Mean time to repair (MTTR): e.g. repair efficiency, downtime minimisation, resource allocation

Downtime tracking: e.g. reason identification, productivity analysis, cost implications

Scrap and rework percentages: e.g. efficiency monitoring, waste management, process improvement

Real-time manufacturing dashboards: e.g. data visualisation, on-the-go insights, strategic decision-making

Digital twin simulations: e.g. process replication, virtual testing, predictive modelling

Process performance benchmarking: e.g. comparison analysis, industry standards, improvement goals

Data analytics for process improvement: e.g. trend analysis, performance metrics, optimisation insights.

Integration of emerging technologies:

IoT and smart sensors: e.g. device connectivity, data acquisition, remote monitoring

Predictive maintenance: e.g. failure prevention, operational efficiency, life cycle management

Automation: technologies (e.g. artificial intelligence (AI), machine earning (ML), robotics); purpose (e.g. repetitive tasks, precision improvement, efficiency increase, traceability enhancement, increased transparency, real-time data generation).

LO3 **Explore the sustainability considerations for organisations manufacturing MedTech devices**

Materials and energy use:

Biodegradable plastics: e.g. eco-friendly, reduced impact, regulatory compliance

Recycled materials: e.g. resource efficiency, environmental sustainability, waste reduction

Energy efficiency measures: e.g. green manufacturing, emissions control, resource conservation

Cleanroom implications: e.g. contamination avoidance, high purity, stringent conditions, ISO 13485, 14644 compliances

Sterile packaging implications: e.g. EU Medical Device Regulation (MDR 2017/745) compliance, sterility maintenance, protective packaging.

Waste management:

Circular economy principles: e.g. resource reuse, product life extension, reduced waste

Zero waste initiatives: e.g. waste elimination, recycling commitment, environmental impact

Material reclamation processes: e.g. resource recovery, recycling systems, sustainability strategies.

Life cycle management:

Environmental impact assessment: e.g. ecosystem protection, sustainability evaluation, compliance

End-of-life strategies: e.g. disposal planning, recycling, life cycle extension

Sustainable supply chain practices: e.g. responsible sourcing, ethical considerations, efficiency.

Sustainability and circular manufacturing:

Low environmental impact materials: e.g. sustainability, eco-friendliness, performance

Recyclable components: e.g. material reuse, life cycle management, waste minimisation

Packaging optimisation: e.g. eco-friendly, cost-efficient, protective packaging

Regulatory compliance: e.g. safety standards, approval processes, biocompatibility

Monomaterials for easy recycling: e.g. single-material designs, recycling ease

Packaging innovations: e.g. biodegradable options, minimal use, environmental benefits.

Single-use device redesign:

EU MDR Article 17 considerations: safety standards, reprocessing guidelines, compliance

Safety and performance maintenance: e.g. consistent quality, regulatory adherence, reliability

Sterilisation and cleaning processes: e.g. sanitisation protocols, contamination prevention, usability.

LO4 **Develop a regulatory-compliant advanced manufacturing process for an identified medical device**

Process development steps:

Research and development: e.g. device innovation, technology exploration, prototype creation

Prototype assessments: e.g. design evaluation, functionality testing, improvement strategies

Feasibility considerations: e.g. practicality, cost-effectiveness, scalability

Functional requirements: e.g. performance criteria, operational parameters, user needs, technical specifications, design constraints

Usage context: e.g. clinical environment, user interaction, device application, healthcare setting, patient demographics

Risk assessment: e.g. risk classification (low, moderate, high); hazard identification procedures (biological, mechanical, electrical risks); design failure mode and effects analysis (DFMEA) frameworks, hazard severity ranking, risk mitigation matrices, product life cycle risk maps.

Material selection:

Biocompatibility issues: e.g. material safety, biological interaction, regulatory compliance

Mechanical properties: e.g. strength, durability, performance characteristics

Cost strategies: e.g. affordability, value optimisation, budget management.

Process testing and implementation:

Quality assurance protocols: e.g. verification, validation, standards adherence

Regulatory compliance: e.g. legal requirements, industry standards, certification

Pilot production setups: e.g. trial runs, efficiency testing, system refinement.

Manufacturing for sterility and cleanliness:

Controlled environments: e.g. contamination avoidance, high purity, stringent conditions

ISO standards: e.g. 13485, 14644; cleanliness levels, Class 7 and 8 compliance

Production protocols: e.g. regulated processes, continuous monitoring, standards implementation.

Technical documentation and traceability:

Compliance tracking: e.g. documentation, quality systems, standardisation

Stakeholder collaboration: e.g. industry partnerships, team coordination, strategic alliances

ISO 13485 and MDR requirements: e.g. process documentation, regulatory verification, audit readiness

Traceability: e.g. recall processes, contamination investigation, market release controls

Conformance evidence: e.g. SOP compliance, process recording, personnel training verification.

Learning Outcomes and Assessment Criteria

<table>
<tr><th>Pass</th><th>Merit</th><th>Distinction</th></tr>
<tr><td colspan="2">LO1 Review a range of advanced manufacturing techniques in the MedTech sector</td><td rowspan="2"></td></tr>
<tr><td>P1 Review, using a range of real-world case studies, a range of advanced manufacturing techniques used in the MedTech sector.

P2 Discuss, using a range of real-world case studies, a range of advanced laser techniques used in the MedTech sector.</td><td>M1 Justify, using a range of real-world case studies, the importance of advanced manufacturing techniques in the MedTech sector.</td></tr>
<tr><td colspan="2">LO2 Discuss the optimisation of manufacturing techniques within the MedTech sector</td><td rowspan="4">LO2 and LO3

D2 Critically evaluate, using a range of real-world case studies, the effectiveness of optimisation techniques and sustainability considerations for manufacturing organisations within the MedTech sector.</td></tr>
<tr><td>P3 Discuss, using a range of real-world case studies, how manufacturing techniques can be optimised in the MedTech sector.

P4 Review, using a range of real-world case studies, the application of data-driven manufacturing metrics and integration of emerging technologies to the optimisation of manufacturing techniques in the MedTech sector.</td><td>M2 Analyse, using a range of real-world case studies, the optimisation of manufacturing techniques within the MedTech sector.</td></tr>
<tr><td colspan="2">LO3 Explore the sustainability considerations for organisations manufacturing MedTech devices</td></tr>
<tr><td>P5 Explore, using a range of real-world case studies, the sustainability considerations for material use for manufacturing organisations in the MedTech sector.

P6 Discuss, using a range of real-world case studies, the sustainability implications for process management for manufacturing organisations in the MedTech sector.</td><td>M3 Justify, using a range of real-world case studies, the importance of sustainability considerations for manufacturing organisations within the MedTech sector.</td></tr>
</table>

Pass	Merit	Distinction
LO4 Develop a regulatory-compliant advanced manufacturing process for an identified medical device		
P7 Develop a regulatory-compliant advanced manufacturing process for an identified MedTech scenario. **P8** Present the advanced manufacturing process to a range of relevant stakeholders to gather feedback on how well the process complies with the relevant regulations.	**M4** Justify the decisions made in the development of the regulatory-compliant advanced manufacturing process, based on your own assessment as well as the stakeholder feedback.	**D3** Critically evaluate the effectiveness of the developed advanced manufacturing process in complying with the relevant regulations, identifying strengths and areas for improvement.

Recommended Resources

Textbooks

Jiang, J., Wu, D., Zhang, Y. and Dai, X. (2024) *Medical Robot Technology*. Singapore: Springer Nature.

Kumar, A. and Katiyar, J.K. (2025) *Micro- and Biofluidics: Structure, Properties, Technology and Spotlight into the Future*. Baco Raton: CRC Press.

Mukhopadhyay, M. and Kuila, A. eds. (2022) *Nanomaterials in Clinical Therapeutics: Synthesis and Applications*. Hobboken: John Wiley & Sons.

Suhag, D., Kaushik, S. and Taxak, V.B. (2024) *Handbook of Biomaterials for Medical Applications, Volume 1: Fundamentals*. Singapore: Springer Nature.

Suhag, D. (2024) *Handbook of Biomaterials for Medical Applications, Volume 2: Applications.* Singapore: Springer Nature.

Websites

www.keyence.co.uk/products/marker/laser-marker/resources/laser-marking-resources/what-is-laser-texturing-and-how-is-it-used.jsp	Keyence What Is Laser Texturing & How Is It Used? (Article)
www.mddionline.com/design-engineering/medtech-miniaturization-how-tiny-devices-make-a-big-impact	Medical Device and Diagnostics Industry Medtech Miniaturization: How Tiny Devices Make a Big Impact (Article)
www.mdpi.com/2079-6412/11/2/124	MDPI Laser Surface Texturing for Biomedical Applications: A Review (Review)
www.medicaldesignbriefs.com/component/content/article/52396-the-role-of-mems-in-next-gen-medical-devices	Medical Design Briefs The Role of MEMS in Next-Gen Medical Devices (Podcast)
www.medtecheurope.org/environmental-and-social-sustainability/sustainable-materials-and-substance-innovation/	MedTech Europe Sustainable materials and substance innovation (Resource)

www.mpo-mag.com/enabling-quality-by-design-in-medical-device-manufacturing/	Medical Product Outsourcing Enabling Quality by Design in Medical Device Manufacturing (Review)
www.mpo-mag.com/exclusives/data-driven-manufacturing-in-the-medical-device-sector/	Medical Product Outsourcing Data-Driven Manufacturing in the Medical Device Sector (Review)
www.mpo-mag.com/exclusives/innovations-in-biocompatible-materials-for-medical-devices/	Medical Product Outsourcing Innovations In Biocompatible Materials For Medical Devices (Article)
www.mpo-mag.com/exclusives/recycling-challenges-and-innovations-for-medical-plastics/	Medical Product Outsourcing Medical Product Outsourcing Innovations In Biocompatible Materials For Medical Devices (Article)
www.sciencedirect.com/science/article/pii/S2238785425005034	Science Direct Recent advances and future prospects of laser welding technology for polymeric materials: A review (Review Article)

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 402: Quality Management Systems (ISO 13485)

Unit 403: Risk Management (ISO 14971)

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 408: Designing a MedTech Project

Unit 505: Manufacturing Processes

Unit 510: Good Practices in MedTech

Unit 511: Hardware, Robotics and Autonomous Systems in MedTech

Unit 514: Emerging Trends and Technologies.

Unit 516: Work-Based Experience

Unit code: **R/651/7122**

Unit level: **5**

Credit value: **15**

Introduction

The MedTech industry is a dynamic and rapidly evolving sector that demands practical experience and hands-on skills. This unit is designed to provide students with real-world exposure to the MedTech environment. By engaging in work placements, students will gain valuable insights into the operational, technical and administrative aspects of the industry. This unit is crucial for students aspiring to build a career in MedTech, offering them the opportunity to apply theoretical knowledge in practical settings and develop essential professional competencies.

The primary aim of this unit is to provide students with firsthand experience of the MedTech sector through the undertaking of a real-world work placement. The work placement aims to give students the opportunity to consider, plan, undertake and review their professional conduct to help develop key skills such as communication, problem solving and adaptability. This practical approach ensures that students gain a comprehensive understanding of the workplace, enhancing their employability and readiness to meet industry demands.

The unit contains a range of topics essential for a successful work-based experience in MedTech. Key areas of focus include preparation for the work placement by examining types of work experience, working environments and how to prepare for placements. Once in the work placement, students will review the technological and cultural changes in the workplace, the professional skills and behaviours required, and key attributes for success in the workplace. Once the work placement has been completed, students will explore the importance of reflection and feedback in determining the next steps to be taken for their professional development. These topics are designed to help equip students with the skills needed to pursue a career in the MedTech industry.

Upon successful completion of this unit, students will have developed critical skills in workplace communication, teamwork, problem solving and professional conduct. These skills are directly linked to roles within the MedTech sector, such as Biomedical Engineer, Clinical Applications Specialist, Regulatory Affairs Associate and Quality Control Technician.

Learning Outcomes

By the end of this unit a student will be able to:

LO1 Describe the key aspects of work experience in the MedTech sector

LO2 Report on the changing nature of work within the MedTech sector

LO3 Undertake a work experience placement within the MedTech sector

LO4 Review professional conduct and the learning experience following a placement in the MedTech sector.

Essential Content

LO1 **Describe the key aspects of work experience in the MedTech sector**

Types of work experience:

Definitions, including work experience, work placement, work placement types (e.g. apprentice, junior, observer, internship, sandwich year, gap year, work shadowing, site visits, company visits, field trips, vacation placements; criteria for suitable and viable placements).

Working environments:

Types of workplace including office, remote, hybrid, client-based; working cultures (e.g. hierarchy, creative, technical, customer focused, market driven, employee focused, innovative, result driven); company practices (e.g. flexible hours, diversity and inclusivity, team focused, employee support, CPD/training and development, learning opportunities).

Sectors:

e.g. diagnostics, therapeutics, digital health, biotechnology, healthcare IT, orthopaedics, cardiology, radiology, neurology, oncology, respiratory, surgical, implants, assistive, dental, ophthalmic, rehabilitation, self-care, laboratory and research; associated tasks and performance measures and outcomes, legislative engagement for work experience and placements.

Purpose:

Organisational objectives; mission statements; relevant legislation, e.g. Medical Device Regulation (MDR), In Vitro Diagnostics Regulation (IVDR).

Preparation for placement:

Key skills required for successful placements, including communication, teamwork and time management; CV writing, job applications and interview techniques in securing placements; employer expectations; candidate expectations.

LO2 **Report on the changing nature of work within the MedTech sector**

Technological changes:

Analysis of data, Internet of Things (IoT) for decision-making, databases, streamlined communication, cloud computing, blockchain technology, developing an online profile, video conferencing software (e.g. Skype, Teams, Zoom), 5G deployment, mobile applications, wearable technologies, time management, monitoring and recording technologies, artificial intelligence, augmented reality, virtual reality.

Productivity improvements:

e.g. higher throughput, completing tasks faster, multitasking.

Efficiency improvements:

e.g. increased automation, fewer staff, reduced error rates, faster response times, improved data access, e.g. retrievals, processing, reporting.

Cultural changes:

Collaboration within a diverse structure, flexible/hybrid working, workplace rights, types of unions, mental health and wellbeing support, data-driven decision-making, privacy and ethical considerations, adoption of greener practices (e.g. reducing paper, energy efficient facilities, greener deployment exercises), inclusivity and diversity considerations, LGBTQ+, integration, differentiation and fragmentation, organisational climate, psychological safety, whistleblowing.

Key attributes for success in the MedTech sector:

e.g. creativity, innovative solutions and problem solving, unconventional thinking, novel approaches, preparedness for failure, acceptance of setbacks, continuous improvement, personal and professional development, staying current with advancements, continuous learning, persistence through challenges, focus and motivation, overcoming regulatory hurdles.

Career development:

Career progression, CPD, skills training, employer-led training, employee training, employer expectations of key employability skills (e.g. interpersonal skills, communication skills, critical thinking, presentation skills, leadership skills, mentorship skills, teamwork, soft skills versus hard skills).

LO3 **Undertake a work experience placement within the MedTech sector**

Professional skills:

Negotiation, communication methods and accountable actions, persuasive behaviours and endorsements, routine work, performance indicators, value for money, digital literacy (e.g. internet use, email use, office applications, file organisation), analytical thinking, policy development, social understanding, stakeholder management, resource allocation, conflict resolution.

Professional behaviours:

Professionalism, including spoken, written, appearance, accountability, respectful conduct, honesty and ethics, positive attitude, time keeping, literacy and numeracy, timewasting and effective time management, communication and interaction, problem solving, accepting feedback, responding to feedback, neatness, organisation of workspace, respect for equipment.

Undertaking placement:

Agreed actions and appreciation of code of practice, log of actions, activities and learning moments, setting SMART targets and objectives

Employer expectations: e.g. starting and stopping times, number of breaks, employee expectations, skills learned

Employee expectations: e.g. use of facilities, including canteen, bathrooms; mentors, support, liaison officer, accessible tasks, skills learned, networking opportunities, project exposure

Legislation compliance: e.g. health and safety, UK GDPR, Computer Misuse Act, risk assessment, MedTech regulations (e.g. ISO 13485, ISO 14971, MDR/IVDR).

Types of feedback:

Feedback for beneficial impact, feedback evaluation, methods of recording for meaningful future engagement, effective and SMART practices.

Feedback methods, including verbal, written (e.g. reports, emails, logs, timesheets), questionnaires, surveys, interviews with colleagues.

LO4 **Review professional conduct and the learning experience following a placement in the MedTech sector**

Review:

Work produced, progress made against agreed targets/outcomes, development and exposure to skill development, revisit and review skills audit, comparison of expectations of self and employer, interdepartmental review, building partnerships.

Reflection:

Simplified methods of reflection, 360° perspective of understanding, De Bono's Six Hats, self-assessment of competencies, learning that has taken place, including formal and informal, identifying and maximising future development opportunities, stress management and resilience.

Next steps:

Action plan for future development, types of development plans and monitoring tools (e.g. spreadsheets, job sheets, timesheets, Teams, email tracking, Gantt chart, OneNote, databases, HR software); preferences of types of work following placement; CV and interview preparation.

Learning Outcomes and Assessment Criteria

Pass	Merit	Distinction
LO1 Describe the key aspects of work experience in the MedTech sector		**LO1 and LO2** **D1** Evaluate a range of work experience opportunities that will shape professional development opportunities within the MedTech sector.
P1 Describe a range of work experience opportunities that would develop understanding of work within the MedTech sector. **P2** Explain the requirements and preparation for securing a work placement in the MedTech sector.	**M1** Analyse a diverse range of viable work experience opportunities to demonstrate a broad understanding of the MedTech sector.	
LO2 Report on the changing nature of work within the MedTech sector		
P3 Explain how developments in technology have enhanced employee productivity and efficiency within the MedTech sector. **P4** Discuss the cultural changes and career progression opportunities within the MedTech sector.	**M2** Review how technological changes can lead to career progression opportunities within the MedTech sector.	

Pass	Merit	Distinction
LO3 Undertake a work experience placement within the MedTech sector		**LO3 and LO4** **D2** Evaluate the success of the professional work placement, considering employee and employer expectations, linking it to future career progression.
P5 Identify a range of employee and employer expectations to be achieved in a work placement experience. **P6** Demonstrate professional practice and key skills within the MedTech sector.	**M3** Assess professionalism in the work experience placement, considering employer and employee expectations.	
LO4 Review professional conduct and the learning experience following a placement in the MedTech sector		
P7 Review feedback obtained from the workplace and self-reflection to identify any strengths and weaknesses following the work placement. **P8** Use the results of the feedback review to create a plan for future development.	**M4** Justify the learning plan developed based on feedback review and reflective practice.	

Recommended Resources

Textbooks

Bassot, B. (2024) *The Reflective Journal*. 4th Ed. London: Bloomsbury Publishing.

Beevers, K., Rea, A. and Hayden, D. (2019) *Learning and Development Practice in the Workplace*. 4th Ed. London: Kogan Page.

Fanthome, C. (2004) *Work Placements: A Survival Guide for Students*. Basingstoke: Palgrave Macmillan.

Herbert, I. and Rothwell, A. (2005) *Managing your Placement: A Skills-based Approach.* Basingstoke: Palgrave Macmillan.

Rolfe, G. and Freshwater, D. (2020) *Critical Reflection in Practice*. 2nd Ed. London: Bloomsbury Publishing.

Rook, S. (2015) *Work Experience, Placement and Internships*. Basingstoke: Palgrave Macmillan.

Stewart, A., Owens, R., O'Higgins, N. and Hewitt, A. (2021) *Internships, Employability and the Search for Decent Work Experience.* Cheltenham: Edward Elgar Publishing.

Thompson, S. and Thompson, N. (2023) 3rd Ed. *The Critically Reflective Practitioner*. London: Bloomsbury Publishing.

Websites

forbes.com	Forbes Top Employers Say Millennials Need These Four Skills (General reference)
www://nationalcareers.service.gov.uk/careers-advice/types-of-work-experience	GOV UK How to get work experience (General reference)
prospects.ac.uk	Prospects

Links

This unit links to the following related units:

Unit 401: Introduction to MedTech

Unit 405: Medical Devices

Unit 406: Regulatory Compliance

Unit 408: Designing a MedTech Project

Unit 503: Managing a MedTech Project

Unit 508: Professional Development

Unit 510: Good Practices in MedTech.

12.0 Appendices

Appendix 1: Transferable skills mapping

Level 4 Higher National Certificate in MedTech for England: mapping of transferable employability and academic study skills

Transferable skills based on the three domains of competence, and clusters of 21st-century competencies published by the Committee on Defining Deeper Learning and 21st Century Skills,[1] and adapted by Pearson Edexcel.[2]

Table 9: Level 4 Transferable skills mapping

Skill set	**Cognitive skills**							**Intrapersonal skills**				**Interpersonal skills**		
Unit	Problem Solving	Critical Thinking/ Analysis	Decision-making	Effective Communication	Digital Literacy	Numeracy	Creativity	Plan/prioritise	Self-management	Independent Learning	Self-reflection	Teamwork	Leadership	Cultural Awareness
401		x			x					x				x
402		x			x					x				x
403	x	x	x		x		x	x		x				x
404	x	x	x	x	x	x	x	x	x	x	x			

[1] Committee on Defining Deeper Learning and 21st Century Skills (2012) *Education for Life and Work: Developing Transferable Knowledge and Skills in the 21st Century*. Washington DC: National Research Council of the National Academies.

[2] Pearson Edexcel (2018) *Transferable skills: A guide for schools [report]*. London: Pearson Edexcel. Available at: https://qualifications.pearson.com/content/dam/pdf/International GCSE/General/Transferable-Skills-Information-Pack.pdf (Accessed: 13 December 2022).

Skill set	Cognitive skills							Intrapersonal skills				Interpersonal skills		
Unit	Problem Solving	Critical Thinking/ Analysis	Decision-making	Effective Communication	Digital Literacy	Numeracy	Creativity	Plan/prioritise	Self-management	Independent Learning	Self-reflection	Teamwork	Leadership	Cultural Awareness
405		x		x	x	x	x	x		x	x	x	x	
406		x	x	x	x	x	x	x	x	x	x	x	x	x
407	x	x	x	x	x		x	x	x	x	x			x
408	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Level 5 Higher National Diploma in MedTech for England: mapping of transferable employability and academic study skills

Table 10: Level 5 Transferable skills mapping

Skill set	Cognitive skills							Intrapersonal skills				Interpersonal skills		
Unit	Problem Solving	Critical Thinking/ Analysis	Decision-making	Effective Communication	Digital Literacy	Numeracy	Creativity	Plan Prioritise	Self-management	Independent Learning	Self-reflection	Teamwork	Leadership	Cultural Awareness
501	x	x	x		x	x	x	x	x	x	x			x
502	x	x	x	x	x	x	x	x	x	x	x	x	x	x
503	x	x	x	x	x	x	x	x	x	x	x	x	x	x
504	x	x	x	x	x	x	x	x	x	x	x	x	x	x
505	x	x	x	x	x	x	x	x	x	x	x	x	x	
506		x	x		x	x	x			x				x
507	x	x	x	x	x	x	x	x	x	x	x	x	x	x
508	x	x	x	x	x		x	x	x	x	x	x	x	x
509	x	x	x	x	x	x	x	x	x	x	x	x	x	
510	x	x	x	x	x	x	x	x	x	x	x	x	x	
511		x			x	x				x				

Skill set	Cognitive skills							Intrapersonal skills				Interpersonal skills		
Unit	Problem Solving	Critical Thinking/ Analysis	Decision-making	Effective Communication	Digital Literacy	Numeracy	Creativity	Plan Prioritise	Self-management	Independent Learning	Self-reflection	Teamwork	Leadership	Cultural Awareness
512	x	x	x	x	x	x	x	x	x	x	x	x	x	x
513	x	x	x	x	x	x	x	x	x	x	x	x	x	
514	x	x	x	x	x	x	x	x	x	x	x	x	x	x
515	x	x	x	x	x	x	x	x	x	x	x	x	x	
516		x	x	x	x		x	x	x	x	x	x	x	x

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