

Pearson BTEC Level 2 Certificate in the Principles and Practice for Pharmacy Support Staff

Specification

BTEC Specialist qualification
First teaching September 2020

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ISBN 978 1 446 96815 4

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1 Introducing BTEC Specialist qualifications

What are BTEC Specialist qualifications?

BTEC Specialist qualifications are work-related qualifications available from Entry to Level 3 in a range of sectors. They give learners the knowledge, understanding and skills they need to prepare for employment in a specific occupational area. The qualifications also provide career development opportunities for those already in work.

BTEC Specialist qualifications put learning into the context of the world of work, giving learners the opportunity to apply their research, skills and knowledge in relevant and realistic work contexts. This applied, practical approach means that learners develop the knowledge, understanding and skills they need for career progression or further study.

Specialist qualifications can be offered as full-time or part-time courses in schools, colleges and training centres, and through employers.

Sizes of BTEC Specialist qualifications

For all regulated qualifications, Pearson specifies a total estimated number of hours that learners will require to complete and show achievement for the qualification – this is the Total Qualification Time (TQT). The TQT value indicates the size of a qualification.

Within the TQT, Pearson identifies the number of Guided Learning Hours (GLH) we estimate a centre delivering a qualification might provide. Guided learning means activities, such as lessons, tutorials, online instruction, supervised study and giving feedback on performance, that directly involve tutors and assessors in teaching, supervising and invigilating learners. It also includes the time required for learners to complete external assessment under examination or supervised conditions.

In addition to guided learning, other required learning directed by tutors or assessors includes private study, preparation for assessment and undertaking assessment when not under supervision, such as preparatory reading, revision and independent research.

As well as TQT and GLH, qualifications can also have a credit value – equal to one tenth of the TQT, rounded to the nearest whole number.

TQT and credit values are assigned after consultation with the employers and training providers delivering the qualifications.

BTEC Specialist qualifications are generally available in the following sizes:

- Award – a qualification with a TQT value of 120 or less
- Certificate – a qualification with a TQT value in the range of 121–369
- Diploma – a qualification with a TQT value of 370 or more.

2 Qualification summary and key information

Qualification title	Pearson BTEC Level 2 Certificate in the Principles and Practice for Pharmacy Support Staff
Qualification Number (QN)	603/6166/9
Regulation start date	17/07/2020
Operational start date	01/09/2020
Approved age ranges	16–18 19+ Please note that sector-specific requirements or regulations may prevent learners of a particular age from taking this qualification. Please see <i>Section 6 Access to qualifications</i> .
Total qualification time (TQT)	250 hours.
Guided learning hours (GLH)	150 hours.
Credit value	25.
Assessment	Internal assessment
Grading information	The qualification and units are at a Pass grade.

Qualification title	Pearson BTEC Level 2 Certificate in the Principles and Practice for Pharmacy Support Staff
Entry requirements	No prior knowledge, understanding, skills or qualifications are required before learners register for this qualification. However, centres must follow the guidance in <i>A guide to recruiting learners onto Pearson qualifications</i> (see Section 6 Access to qualifications).
Funding	Qualifications eligible and funded for post-16-year-olds can be found on the funding Hub. The Apprenticeship funding rules can be found at www.gov.uk

Centres will need to use the Qualification Number (QN) when they seek public funding for their learners. The qualification title, unit titles and QN will appear on each learner's final certificate. Centres should tell learners this when recruiting them and registering them with Pearson. There is more information about certification in our *UK Information Manual*, available on our website: qualifications.pearson.com

3 Qualification purpose

Qualification objectives

The Pearson BTEC Level 2 Certificate in the Principles and Practice for Pharmacy Support Staff is for learners who work in, or who are intending to work in, the role of pharmacy support staff within a pharmacy setting, and want to achieve the requirements for the education and training of pharmacy support staff as set out by the General Pharmaceutical Council (GPhC).

Pharmacy Support Staff are non-registered but are accountable to their employer, who must meet the regulatory requirements for the education and training of support staff, as set by the General Pharmaceutical Council (GPhC), effective from October 2020.

Pharmacy Support Staff work in many different roles across different settings, including (but not exclusively); registered pharmacies, community services, justice (the Prison Service), GP practices, dispensing doctors' practices, care homes and clinical commissioning groups, hospitals, mental health and in the pharmaceutical industry.

Pharmacy Support Staff play a key role in supporting the work of pharmacy professionals, such as the Pharmacy Technician and Pharmacist, in providing safe and effective pharmacy services. The actual work setting will determine the work activity that the Pharmacy Support Staff undertakes.

The qualification gives learners the opportunity to:

- develop the fundamental technical skills and underpinning knowledge and understanding to perform their particular role safely and effectively. For details of the units included in this qualification, please see *Section 4, Qualification Structure*.
- develop appropriate attitudes and behaviours that will support personal success in their job role and the long-term success of their organisation.
- develop a range of interpersonal and intrapersonal skills, to support progression to, and success in, further study and career advancement.
- achieve a nationally recognised Level 2 qualification, recognised by the General Pharmaceutical Council (GPhC).

Progression opportunities

Learners who achieve the qualification, can progress to the Pearson BTEC Level 3 Diploma in Principles and Practice for Pharmacy Technicians, if they meet the entry requirements.

With further training and development, learners can progress to a more senior or complex job role in pharmacy or the healthcare sector.

Industry support and recognition

This qualification is supported by the General Pharmaceutical Council (GPhC), Health Education England, Health Education and Improvement Wales (HEIW), Skills for Health (SfH), South Eastern Regional College and Bradford College.

4 Qualification structure

Pearson BTEC Level Certificate in the Principles and Practice for Pharmacy Support Staff

The learner will need to meet the requirements outlined in the table below before Pearson can award the qualification.

Minimum number of units that must be achieved	5
Number of mandatory units that must be achieved	4
Number of optional units that must be achieved	1

Unit number	Mandatory units	Level	Credit	Guided learning hours
1	Person-centred Care and Communication	2	5	30
2	Principles of Health and Safety for Pharmacy Support Staff	2	3	15
3	Effective Teamwork within Pharmacy Services	2	3	15
4	Personal Development for Pharmacy Support Staff	2	4	20
Unit number	Optional units	Level	Credit	Guided learning hours
5	Dispensing and Supply of Prescribed Medicines and Medicinal Products	2	10	70
6	Managing Pharmaceutical Stock	2	10	70
7	Principles of Safe Preparation and Manufacturing of Medicines and Pharmaceutical Products	2	10	70
8	Selling Over the Counter Medicines and Medicinal Products	2	10	70

5 Centre resource requirements

As part of the approval process, centres must make sure that the resource requirements below are in place before offering the qualification.

General resource requirements

- Centres must have the appropriate physical resources to support delivery and assessment of the qualification.
- Learners must be employed, either full-time or part-time, in a pharmacy. They must be enrolled on a training course as soon as practically possible and within three months of commencing their role.
- Learners undertaking this qualification will need access to a pharmacy, with a minimum placement of at least 14 hours per week, and to a registered pharmacy professional to act as a supervisor or mentor.
- Staff delivering this qualification should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.
- Centres must meet any specific human and physical resource requirements outlined in the Assessment Principles in *Annexe A*. Staff assessing learners must meet the occupational competence requirements in the Assessment Principles and the staff qualification requirements set out in Appendix 1 of *Annexe A*.
- Staff involved in the assessment process must have relevant expertise and occupational experience. This includes having:
 - substantial knowledge and understanding of the subject areas appropriate to the level, breadth and content of the units. This can be evidenced through having a relevant qualification or current (within three years) occupational experience that is at an equivalent or higher level than the level of the qualification(s) that is being assessed
 - a qualification in teaching or assessing and/or internal quality assurance or current (within three years) experience of assessing or internal verification
 - GPhC registration as a pharmacy professional.

- There must be systems in place that ensure continuing professional development (CPD) for staff delivering and assessing the qualification. All staff delivering the course must understand their role and be given support to carry out their work effectively.
- Centres must have appropriate health and safety policies, procedures and practices in place for the delivery and assessment of the qualification.
- Centres must have appropriate health and safety policies in place that relate to the use of equipment by learners.
- Centres must have robust internal verification systems and procedures in place to ensure the quality and authenticity of learners' work, as well as the accuracy and consistency of assessment decisions between assessors operating at the centre. For information on the requirements for implementing assessment processes in centres, please refer to our work-based learning quality assurance handbooks, available in the support section of our website.
- Centres must deliver the qualification in accordance with current equality legislation. For further details on Pearson's commitment to the Equality Act 2010, please see *Section 6 Access to qualifications*. For full details of the Equality Act 2010, please visit www.legislation.gov.uk

The centre's management team must ensure that there are clear and defined structures and processes to manage delivery in an accurate and timely fashion so that the standard is maintained. A schedule of roles and responsibilities must be in operation to ensure that trainee pharmacy support staff are supported in appropriate learning and training environments and in the workplace. For example, each trainee pharmacy support staff will need to be allocated a supervisor in the workplace, with sufficient expertise to oversee their activities. The centre must establish clear lines of accountability and implement reliable processes for identifying and managing risk. For example, in the workplace, trainee pharmacy support staff must be made aware of the appropriate person to whom they should refer issues outside their scope of competence.

There must be agreements in place outlining the roles and responsibilities of all those involved in delivering a programme. Agreements must also be in place between centres and the workplace regarding the roles and responsibilities for assessment.

The centre must ensure that the IQA processes are sufficiently robust in order to monitor and evaluate the standard of teaching, learning and assessment to make sure that quality is maintained across all learning environments. It is important that these IQA processes sample the full range of staff, processes and, indirectly, learners, to ensure that quality outcomes are maintained. There is no definition of a sample size, but instead this will be dictated by the risk presented by the staff, assessment methods and outcomes. There will be a system of external quality assurance provided by Pearson, which will review the accuracy of the assessment decisions and the influence of IQA processes in order to maintain a secure certification process.

In all the learning and training environments, there must be:

- appropriately qualified and experienced staff (qualification requirements for staff are set out in Appendix 1 of *Annexe A*)
- sufficient staff from relevant disciplines to deliver the programme and support pharmacy support staffs' learning
- sufficient resources to deliver the programme
- facilities that are fit for purpose
- access to appropriate learning resources.

Patient safety must come first in all circumstances. Learners must be supervised using an agreed system in all learning and training environments, to ensure patient safety at all times. Learners must carry out tasks only in which they are competent, or that they are learning under supervision in which to be competent, so that patient safety is not compromised.

Each learner must have a learning agreement covering all the learning and training environments. This must outline roles, responsibilities and lines of accountability, and must say how learners will be supported during the programme. Centres must explain how they will be reassured that learning agreements will be implemented in full.

Each learner must be supported as a trainee in the workplace. There must be systems in place for liaising with employers regularly on the progress of learners.

It is important that learners are provided with a clear induction that identifies how the course will be taught and assessed. Learners should have a clear understanding of the staff they would speak to for support, guidance and, if necessary, to make an appeal or complaint. Trainee pharmacy support staff should be suitably supervised in all aspects of their work to ensure that their practice is safe and accurate. Their supervisor should monitor their workload to ensure that it is appropriate and realistic, and reflective of their experience. Time to learn must be sufficient and provide effective opportunity to complete work and collect or produce satisfactory evidence. Learners must be supported effectively in their roles to ensure that they are exposed to sufficient experiences to complete the qualification. Learners must be able to access personal and academic support and the supervisor must signpost this support clearly to learners at induction and through the course. The supervisor must ensure that learners have sufficient access to resources in order to support their learning and make effective progress. Resources will include (though they are not limited to) appropriate information technology hardware and software, relevant and current textbooks, and sufficient experiences in the pharmacy workplace.

Learners must receive appropriate and timely feedback on their performance in order to support their development as trainee pharmacy support staff.

The following must also be provided for learners:

- systems that enable them to meet regularly with workplace colleagues in order to discuss and document their progress
- access to pharmacy professionals who are able to act as role models and give support and guidance
- the opportunity to work in multidisciplinary teams.

The supervisor of trainee pharmacy support staff must be able to provide clear signposting to the support available to them, covering academic study, general welfare and career advice. This support should be discussed at length at induction and revisited frequently throughout the course.

All centres and employers must have procedures in place to deal with concerns. This may include concerns about the learners themselves, the environment they are working or training in or the practice of those they come into contact with. There must also be clear procedures for learners to raise concerns. Any concerns must be dealt with promptly, with documented action taken when appropriate. Learners must be made aware of GPhC's guide to raising concerns about pharmacy education and training, which can be found here:

<https://www.pharmacyregulation.org/education/raising-concerns-about-pharmacy-education-and-training>

There must be a quality management structure in place to monitor all aspects of the programme, including planning, assessment and feedback, which must be monitored, reviewed and evaluated on a systematic basis and established at the beginning of the programme. This sampling strategy may expand as risk and practice develops. When issues are identified, they must be documented and addressed within agreed timescales that ensure that neither learner progress nor accurate assessment decisions are hindered. Staff responsible for the oversight and implementation of quality management systems should be identified and be responsible for timely reporting and analysis of the outcomes.

Programme monitoring and review must take into account the external environment, especially pharmacy, to make sure that programmes stay up to date as they are delivered. Programmes must be revised when there are significant changes in practice to make sure they are up to date. For example, any changes to legislation relating to pharmacy should be promptly identified and the most up-to-date legislation referenced in the programme.

6 Access to qualifications

Access to qualifications for learners with disabilities or specific needs.

Equality and fairness are central to our work. Our *Equality, diversity and inclusion policy* requires all learners to have equal opportunity to access our qualifications and assessments, and that our qualifications are awarded in a way that is fair to every learner.

We are committed to making sure that:

- learners with a protected characteristic (as defined by the Equality Act 2010) are not, when they are taking one of our qualifications, disadvantaged in comparison to learners who do not share that characteristic
- all learners achieve the recognition they deserve from their qualification and that this achievement can be compared fairly to the achievement of their peers.

For learners with disabilities and specific needs, the assessment of their potential to achieve the qualification must identify, where appropriate, the support that will be made available to them during delivery and assessment of the qualification.

Centres must deliver the qualification in accordance with current equality legislation. For full details of the Equality Act 2010, please visit www.legislation.gov.uk

Reasonable adjustments and special consideration

Centres are permitted to make adjustments to assessment to take account of the needs of individual learners. Any reasonable adjustment must reflect the normal learning or working practice of a learner in a centre or a learner working in the occupational area.

Centres cannot apply their own special consideration – applications for special consideration must be made to Pearson and can be made on a case-by-case basis only.

Centres must follow the guidance in the Pearson document *Guidance for reasonable adjustments and special consideration in vocational internally assessed units*.

7 Programme delivery

Centres are free to offer this qualification using any mode of delivery that meets learners' and employers' needs. It is recommended that centres make use of a wide range of training delivery methods, including direct instruction in classrooms, simulated demonstrations, research or applied projects, e-learning, directed self-study, field visits and role play. Whichever mode of delivery is used, centres must make sure that learners have access to the identified resources and to the subject specialists delivering the units.

Centres must adhere to the Pearson policies that apply to the different models of delivery. Please refer to our *Collaborative and consortium arrangements for the delivery of vocational qualifications policy*, available on our website.

Those planning the programme should aim to enhance the vocational nature of the qualification by:

- spending time with employers to better understand their organisational requirements and the methods of training that are most suitable, taking into consideration their available resources and working patterns
- collaborating with employers to ensure that learners have opportunities in the workplace to implement the knowledge and skills developed through the training programme
- developing up-to-date and relevant teaching materials that make use of scenarios relevant to the sector and relevant occupation
- giving learners the opportunity to apply their learning in realistic practical activities
- having regular meetings with employers to discuss learner progress, providing feedback and agreeing how any issues will be resolved
- developing projects or assessments with input from employers
- using 'expert witness' reports from employers to support assessment
- making full use of the variety of experience of work and life that learners bring to the programme.

Where legislation is taught, centres must ensure that it is current and up to date.

Elements of good practice

- Carrying out a thorough induction for learners to ensure that they completely understand the programme and what is expected of them. The induction could include, for example, the requirements of the programme, an initial assessment of current competency levels, assessment of individual learning styles, identification of training needs, an individual learning plan, details of training delivery and the assessment process.
- Having regular progress meetings with learners to keep them engaged and motivated, and ensuring that there are open lines of communication among all those involved in delivering the training and assessment.
- Using flexible delivery and assessment approaches to meet the needs of learners and the organisational context and requirements, through the use of a range of approaches, for example virtual learning environments (VLEs), online lectures, video, printable online resources, virtual visits, webcams for distance training, eportfolios.
- Balancing on-the-job and off-the-job training. Trainers need to use a range of teaching and learning methods to deliver this training effectively while still meeting varying learner needs. Examples of teaching and learning methods for off-the-job training include: enquiry-based learning, real-world problem solving, reflective practice, questioning and discussions, demonstration, practising ('trial and error'), simulation and role play, peer learning and virtual environments. Trainers also need to plan opportunities for the development and practising of skills on the job. The on-the-job element of the programme offers opportunities for assessment and plays an important role in developing the learner's routine expertise, resourcefulness, craftspersonship and professionalism. It is important that there is intentional structuring of practice and guidance to supplement the learning and development provided through engagement in everyday work activities. Teaching and learning methods, such as coaching, mentoring, shadowing, observation, collaboration and consultation, could be used in this structured on-the-job learning.
- Developing a holistic approach to assessment by matching evidence to the required competencies, as appropriate and, wherever possible, to reduce the assessment burden on learners and assessors. It is good practice to draw up an assessment plan that aligns the competencies to be achieved with the learning process and which indicates how and when assessment will take place.
- Discussing and agreeing with the learner and their line manager suitable times, dates and work areas where assessment will take place. Learners and managers should be given regular and relevant feedback on performance and progress.

- Ensuring that learners are allocated a mentor in the workplace to assist them in the day-to-day working environment and to act as contact for the assessor/trainer. Preferably this would be the same person as the supervising pharmacist/pharmacy technician, though it could be a different person if working hours or practices require it.
- Ensuring that sufficient and relevant work is given to learners in order to allow them to gain wider employment experience and to enable them to develop, within their contracted working hours, the competencies and the related knowledge, skills and behaviours required for this qualification.

Feedback from learners must be a part of monitoring, review and evaluation processes. For example, online questionnaires could be used to capture learner feedback on the quality of teaching and learning materials, giving the centre the opportunity to identify good practice and address any issues.

Equality and diversity must be embedded in programme design and delivery. Equality and diversity data must be used in designing and delivering programmes, and in planning the whole experience of being pharmacy support staff. For example, by monitoring the equality characteristics of learners registered on a programme, centres may find that certain groups are under-represented and may then be able to discover and address the reasons for this.

Centres must deliver the qualification in accordance with current equality legislation. For further details on Pearson's commitment to the Equality Act 2010, please see *Section 6 Access to qualifications*. For full details on the Equality Act 2010, please visit www.legislation.gov.uk

8 Assessment

The table below gives a summary of the assessment methods used in the qualification.

Units	Assessment method
All units	Internal assessment (centre-devised assessments).

In administering internal assessments, centres need to be aware of the specific procedures and policies that apply to, for example, registration, entries and results. There is more information in our *UK Information Manual*, available on our website.

Language of assessment

Assessments for all units are in English only.

A learner taking the qualification may be assessed in British or Irish Sign Language where it is permitted for the purpose of reasonable adjustment.

Further information on the use of language in qualifications is available in our *Use of languages in qualifications policy*, available on our website.

For further information on access arrangements, please refer to the paragraph *Reasonable adjustments to assessments*, in the *Administrative arrangements for internal assessment* section.

Internal assessment

All units in this qualification are internally assessed and subject to external standards verification. This means that centres set and mark the final summative assessment for each unit, using the examples and support that Pearson provides. Centres need to be approved (if they are not already approved) to offer the qualification before conducting assessments. *Section 10 Centre recognition and approval*, gives information on approval for offering this qualification.

Assessment of knowledge units using assignments

For internally-assessed units, the format of assessment is an assignment taken after the content of 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 forms. An assignment is a distinct activity, completed independently by learners, that

is separate from teaching, practice, exploration and other activities that learners complete with direction from tutors and assessors.

An assignment is issued to learners as an assignment brief with a defined start date, a completion date and clear requirements for the evidence that they need to provide.

Assignments can be divided into tasks and may require several forms of evidence. A valid assignment will enable there to be a clear and formal assessment outcome based on the assessment criteria.

Designing effective assignments for knowledge units

Recommended assignments are given in the *Further information for tutors and assessors* section of each knowledge unit. In designing assignments, centres need to work within the structure of the recommended assignments. They need to consider the following points when developing their assignment briefs.

- Centres may choose to combine all or parts of different units into single assignments, provided that all units and all their associated learning outcomes are fully addressed in the programme overall. If this approach is taken, centres need to make sure that learners are fully prepared so that they can provide all the required evidence for assessment and that centres are able to track achievement in their learner records.
- A learning outcome must always be assessed as a whole and should not be split into two or more assignments.
- The assignment must be targeted to the learning outcomes but the learning outcomes and their associated criteria are not tasks in themselves. Criteria are expressed in terms of the outcome shown in the evidence.
- Clear instructions must be provided to the learner about what they are required to do - normally set out through a series of tasks.
- Centres do not have to follow the order of the learning outcomes of a unit in developing assignments but later learning outcomes often require learners to apply the content of earlier learning outcomes, they may also require learners to draw their learning together.
- As assignments constitute the final assessment, they will draw on the specified range of teaching content for the learning outcomes. The specified content is compulsory for teaching and learning. The evidence for assessment need not cover every aspect of the teaching content, as learners will normally be given particular examples, case studies or contexts in their assignments. For example, if a learner is carrying out research on their employer organisation, then they will address all the relevant range of content that applies in that instance.
- The assignment brief must include the vocational scenario or context for the tasks to be completed. There must in addition be a clear audience or purpose for which the evidence is being provided.

To ensure that final assessment decisions meet the required standard, assignments must be fit for purpose as a tool for measuring learning against the defined content and assessment criteria. Centres should make sure that assignments enable learners to produce valid, sufficient, authentic and appropriate evidence that relates directly to the specified criteria in the context of the learning outcomes and unit content.

An assignment that is fit for purpose and suitably controlled is one in which:

- the tasks that the learner is asked to complete provide evidence for a learning outcome that can be assessed using the assessment criteria
- the time allowed for the assignment is clearly defined and is consistent with what is being assessed
- the centre has the required resources for all learners to complete the assignment fully and fairly
- the evidence that the assignment generates is authentic and individual to the learner
- the evidence can be documented to show that the assessment and verification has been carried out correctly.

Forms of evidence

Centres may use a variety of forms of evidence, as long as they are suited to the type of learning outcome that is being assessed. For some units, the practical demonstration of skills is necessary and, for others, learners will need to demonstrate their knowledge and understanding. The units give information on suitable forms of evidence.

Centres may choose to use different forms of evidence to those proposed. Overall, learners should be assessed using varied forms of evidence.

Some of the suitable forms of evidence include:

- written tasks or reports
- projects
- time-constrained simulated activities, with observation records and supporting evidence
- observation and recordings of practical tasks or performance in the workplace
- sketchbooks, work logbooks, reflective journals and workbooks
- presentations with assessor questioning
- witness testimony.

The form(s) of evidence selected must allow:

- the learner to provide all the evidence required for the learning outcomes and the associated assessment criteria

- the learner to produce evidence that is their own, independent work
- a verifier to independently reassess the learner's work to check the assessor's decisions.

For example, when using performance evidence centres need to think about how supporting evidence can be captured through preparation notes, reflective accounts, logbook records, recordings, photographs and task sheets.

Centres need to take particular care that they enable learners to produce independent work. For example, if learners are asked to use real examples, then best practice would be to encourage them to use examples of their own experiences.

For information on the requirements for implementing assessment processes in centres, please refer to our work-based learning quality assurance handbooks, available in the support section of our website.

Assessment of skills units using a portfolio

All skills units in the qualification are assessed through an internally and externally quality-assured portfolio made up of evidence gathered during the course of the learner's work. Each skill unit has specified learning outcomes and assessment criteria. To pass each skills unit, the learner must:

- achieve all the specified learning outcomes
- satisfy all the assessment criteria by providing sufficient and valid evidence for each criterion
- prove that the evidence is their own.

The learner must have an assessment record that identifies the assessment criteria that have been met. The assessment record should be cross-referenced to the evidence provided. The assessment record should include details of the type of evidence and the date of assessment. Suitable centre documentation should be used to form an assessment record.

Forms of evidence

To achieve a skills unit, the learner must gather evidence showing that they have met the required standard specified in the assessment criteria and Pearson's quality assurance arrangements (see *Section 10 Quality assurance of centres*).

The evidence for the skills units can take a variety of forms as indicated below.

- Direct observation of the learner's performance by their assessor (O).
- Outcomes from oral or written questioning (Q&A).
- Products of the learner's work (P).
- Personal statements and/or reflective accounts (RA).
- Professional discussion (PD).
- Authentic statements/witness testimony (WT).
- Simulation (S) where a real-work context does not offer the opportunity for assessment, for example dealing with issues, problems and complaints.
- Expert witness testimony (EWT).

Learners can use the abbreviations in their portfolios for cross-referencing purposes. Learners must provide evidence of their achievement of the knowledge-based learning outcomes and the associated assessment criteria in skills units – achievement cannot be inferred from performance.

Centres must ensure that the assessment methods used are appropriate for the specific learning outcomes and assessment criteria. Before the assessment is conducted, learners may need guidance on the requirements of different command

verbs. This will ensure that the evidence they provide has sufficient breadth and depth to meet the assessment requirements.

Learners can use one piece of evidence to prove their knowledge, skills and understanding across different assessment criteria and/or across different units. It is not necessary for learners to have each assessment criterion assessed separately. The evidence provided for each unit must reference clearly the unit that is being assessed and learners should be encouraged to signpost evidence. Evidence must be available to the assessor, the internal verifier and the Pearson standards verifier.

Any specific evidence requirements for a unit are given in the unit's *Assessment* section. Further guidance on the requirements for centre quality assurance and internal verification processes is available on our website.

Making valid assessment decisions

Authenticity of learner work

An assessor must assess only work that is authentic, i.e. learners' own independent work. Learners must authenticate the evidence that they provide for assessment through signing a declaration stating that it is their own work.

Assessors must ensure that evidence is authentic to a learner, through setting valid assignments and supervising learners during assessment period. Supervision will usually include tutors overseeing the planning stage, supervising a proportion of the assignment and regular discussion with the learner during the assessment. Assessors must take care not to provide direct input, instructions or specific feedback that may compromise authenticity.

Assessors must complete a declaration that:

- the evidence submitted for this assignment is the learner's own
- the learner has clearly referenced any sources used in the work
- they understand that false declaration is a form of malpractice.

Centres may use Pearson templates or their own templates to document authentication.

During assessment, an assessor may suspect that some or all of the evidence from a learner is not authentic. The assessor must then take appropriate action using the centre's policies for malpractice. More information is given later in this section.

Making assessment decisions using unit-based criteria

Assessment decisions for the qualification are based on the specific criteria given in each unit. Assessors make judgements using the assessment criteria and must show how they have reached their decisions in the assessment records. The assessor needs

to make a judgement against each criterion that evidence is present and sufficiently comprehensive.

For example, the inclusion of a concluding section may be insufficient to satisfy a criterion requiring 'evaluation'.

Assessors should use the following information and support in reaching assessment decisions:

- the *Essential information for tutors and assessors* section in each unit, which gives further information on the requirements to meet the assessment criteria
- the centre's Lead Internal Verifier and the assessment team's collective experience
- *Annexe B: Glossary of terms used in assessment criteria.*

When a learner has completed the assessment for a unit, then the assessor will give an assessment outcome for the unit.

To achieve a Pass, a learner must have satisfied all the assessment criteria for the learning outcomes, showing appropriate coverage of the unit content and therefore attainment at the stated level of the qualification. The award of a Pass is a defined level of performance and cannot be given solely on the basis of a learner completing assignments. Learners who do not satisfy the assessment criteria for the units should be reported as Unclassified.

Dealing with late completion of assignments

Learners must have a clear understanding of the centre's policy on completing assignments by the stated deadlines. Learners may be given authorised extensions for legitimate reasons, such as illness at the time of submission, in line with centre policies.

For assessment to be fair, it is important that learners are all assessed in the same way and that some learners are not advantaged by having additional time or the opportunity to learn from others.

If a late completion is accepted, then the assignment should be assessed normally using the relevant assessment criteria.

Issuing assessment decisions and feedback

Once the assessor has completed the assessment process for an assignment, the outcome is a formal assessment decision. This is recorded formally and reported to learners.

The information given to the learner:

- must show the formal decision and how it has been reached, indicating how or where criteria have been met
- may show why attainment against criteria has not been demonstrated

- must not provide feedback on how to improve evidence
- must be validated by an Internal Verifier before it is given to the learner.

Resubmissions and retakes

Learners who do not successfully pass an assignment, are allowed to resubmit evidence for the assignment or to retake another assignment.

Administrative arrangements for internal assessment

Records

Centres are required to retain records of assessment for each learner. Records should include assessments taken, decisions reached and any adjustments or appeals. More information is given in our *UK Information Manual*. We may ask to audit centre records, so they must be retained as specified.

Reasonable adjustments to assessments

Centres are able to make adjustments to assessments to take account of the needs of individual learners, in line with the guidance given in our document *Guidance for reasonable adjustments and special consideration in vocational internally assessed units*. In most instances, adjustments can be achieved by following the guidance, for example allowing the use of assistive technology or adjusting the format of the evidence.

We can advise you if you are uncertain as to whether an adjustment is fair and reasonable. Any reasonable adjustment must reflect the normal learning or working practice of a learner in a centre or a learner working in the occupational area.

There is further information on access arrangements in the Joint Council for Qualifications (JCQ) document *Access arrangements and reasonable adjustments*.

Special consideration

Centres must operate special consideration in line with the guidance given in the Pearson document *Guidance for reasonable adjustments and special consideration in vocational internally assessed units*. Special consideration may not be applicable in instances where:

- assessment requires the demonstration of practical competence
- criteria have to be met fully
- units/qualifications confer licence to practice.

Centres cannot apply their own special consideration – applications for special consideration must be made to Pearson and can be made on a case-by-case basis only.

A separate application must be made for each learner. Certification claims must not be made until the outcome of the application has been received.

Further information on special consideration can be found in the Joint Council for Qualifications (JCQ) document *A guide to the special consideration process*.

Appeals against assessment

Centres must have a policy for dealing with appeals from learners. Appeals may relate to assessment decisions being incorrect or assessment not being conducted fairly. The first step in such a policy is a consideration of the evidence by a Lead Internal Verifier or other member of the programme team. The assessment plan should allow time for potential appeals after learners have been given assessment decisions.

Centres must document all learners' appeals and their resolutions. Further information on the appeals process can be found in the document *Enquiries and appeals about Pearson vocational qualifications and end point assessment policy*, available on our website.

Dealing with malpractice in assessment

Malpractice means 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* available on our website.

The procedures we ask you to adopt vary between units that are internally assessed and those that are externally assessed.

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* 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 above 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.

Learner malpractice

The head of centre is required to report incidents of suspected learner malpractice that occur during Pearson qualifications. We ask centres to complete Joint Council for Qualifications (JCQ) *Form M1* (www.jcq.org.uk/exams-office/malpractice) and email it with any accompanying documents (signed statements from the learner, 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 learners lies with Pearson.

Learners must be informed at the earliest opportunity of the specific allegation and the centre's malpractice policy, including the right of appeal. Learners 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.

Teacher/centre malpractice

The head of centre is required to inform Pearson's Investigations team of any incident of suspected malpractice (which includes maladministration) by centre staff, before any investigation is undertaken. The head of centre is requested to inform the Investigations team by submitting a *JCQ M2 Form* (www.jcq.org.uk/exams-office/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.

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
- 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
- temporarily withholding certification of learners
- placing temporary blocks on registration of learners
- debarring staff members or the centre from delivering Pearson qualifications
- suspending or withdrawing centre approval status.

The centre will be notified if any of these apply.

Pearson has established procedures for centres that are 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 learners and/or members or 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: A guide to the awarding bodies' appeals process.

9 Recognising prior learning and achievement

Recognition of Prior Learning

Recognition of Prior Learning (RPL) is a method of assessment that considers whether a learner can demonstrate that they can meet the assessment requirements for a unit through knowledge, understanding or skills they already possess and so do not need to develop through a course of learning.

Pearson encourages centres to recognise learners' previous achievements and experiences in and outside the workplace, as well as in the classroom. RPL provides a route for the recognition of the achievements resulting from continuous learning.

RPL enables recognition of achievement from a range of activities using any valid assessment methodology. If the assessment requirements of a given unit or qualification have been met, the use of RPL is acceptable for accrediting a unit, units or a whole qualification. Evidence of learning must be sufficient, reliable and valid.

Further guidance is available in our policy document *Recognition of prior learning policy and process*, available on our website.

10 Centre recognition and approval

Centres that have not previously offered BTEC Specialist qualifications need to apply for, and be granted, centre recognition as part of the process for approval to offer individual qualifications.

Existing centres will be given 'automatic approval' for a new qualification if they are already approved for a qualification that is being replaced by a new qualification and the conditions for automatic approval are met.

Guidance on seeking approval to deliver BTEC qualifications is given on our website.

Approvals agreement

All centres are required to enter into an approval agreement with Pearson, in which the head of centre or principal agrees to meet all the requirements of the qualification specification and to comply with the policies, procedures, codes of practice and regulations of Pearson and relevant regulatory bodies. If centres do not comply with the agreement, this could result in the suspension of certification or withdrawal of centre or qualification approval.

11 Quality assurance of centres

For the qualification in this specification, the Pearson quality assurance model will consist of the following processes.

Centres will receive at least one visit from our Standards Verifier, followed by ongoing support and development. This may result in more visits or remote support, as required to complete standards verification. The exact frequency and duration of Standards Verifier visits/remote sampling will reflect the level of risk associated with a programme, taking account of the:

- number of assessment sites
- number and throughput of learners
- number and turnover of assessors
- number and turnover of internal verifiers
- amount of previous experience of delivery.

Following registration, centres will be given further quality assurance and sampling guidance.

For further details, please see the work-based learning quality assurance handbooks, available in the support section of our website:

- *Pearson centre guide to quality assurance – NVQs/SVQs and competence-based qualifications*
- *Pearson delivery guidance & quality assurance requirements – NVQs/SVQs and competence-based qualifications.*

12 Units

Each unit in the specification is set out a similar way. This section explains how the units are structured. It is important that all tutors, assessors, internal verifiers and other staff responsible for the programme review this section.

Units have the following sections.

Unit number

The number is in a sequence in the specification.

Unit title

This is the formal title of the unit that will appear on the learner's certificate.

Level

Units and qualifications have a level assigned to them. The level assigned is informed by the level descriptors defined by Ofqual, the qualifications regulator.

Unit type

This says if the unit is mandatory or optional for the qualification.
See *Section 4 Qualification structure* for details.

Credit value

All units in this qualification have a credit value. The minimum credit value is 1 and credits can be awarded in whole numbers only.

Guided Learning Hours (GLH)

This indicates the number of hours of activities that directly or immediately involve tutors and assessors in teaching, supervising, and invigilating learners, for example lectures, tutorials, online instruction and supervised study. Units may vary in size.

Pearson has consulted with users of the qualification and has assigned a number of hours to this activity.

Unit introduction

This is designed with learners in mind. It indicates why the unit is important, what will be learned and how the learning might be applied in the workplace.

Learning outcomes

The learning outcomes of a unit set out what a learner knows, understands or is able to do as the result of a process of learning.

Assessment criteria

The assessment criteria specify the standard the learner is required to meet to achieve a learning outcome.

Unit content

This section sets out the required teaching content of the unit and specifies the knowledge, skills and understanding required for achievement of the unit. It enables centres to design and deliver a programme of learning that will enable learners to achieve each learning outcome and to meet the standard determined by the assessment criteria.

Where it is designed to support apprenticeships, the unit content is informed by the knowledge and understanding requirements of the relevant Apprenticeship Standard.

Relationship between unit content and assessment criteria

Content is compulsory for internally assessed units except when shown as 'e.g.'. Although it is not a requirement that all of the content is assessed, learners should be given the opportunity to cover it all.

Learners should be asked to complete summative assessment only after the teaching content for the unit or learning outcomes has been covered.

Legislation

Legislation cited in the units is current at time of publication. The most recent legislation should be taught and assessed internally.

Essential information for tutors and assessors

This section gives information to support delivery and the implementation of assessment. It contains the following subsections.

- *Essential resources* – lists any specialist resources needed to deliver the unit. The centre will be asked to make sure that these resources are in place when it seeks approval from Pearson to offer the qualification.
- *Assessment* – for internally-assessed units, it provides recommended assignments and suitable sources of evidence for each learning outcome. It also gives

information about the standard and quality of evidence expected for learners to achieve the learning outcome and pass each assignment. It is important that the information is used carefully alongside the assessment criteria.

Unit 1: Person-centred Care and Communication

Level:	2
Unit type:	Mandatory
Credit value:	5
Guided learning hours:	30

Unit introduction

The aim of this unit is to enable learners to develop their knowledge and understanding of effective communication within pharmacy services in order to provide person-centred care, and their role and responsibilities in relation to safeguarding. They will also develop knowledge and understanding of their role as pharmacy support staff in the promotion of healthy lifestyles. Learners will also develop the skills enabling them to communicate effectively within pharmacy services, handle information, promote and advocate equality, diversity and inclusion and healthy lifestyle programmes.

As pharmacy support staff, you will interact with colleagues, patients, carers and the wider healthcare team, so you will need to develop effective communication skills and person-centred approaches.

You will study the main purposes of effective communication and develop techniques which allow you to determine individuals' needs and adapt information appropriately whilst ensuring confidentiality.

You will explore the reasons which influence the need for diverse, person-centred approaches, such as environmental, cultural, religious and physical/learning disabilities. You will have the opportunity to develop your understanding of safeguarding and how to raise concerns.

In this unit, you will learn about the relationship between lifestyle, health and wellbeing– factors that impact on every individual, on communities, and on society as a whole. Focusing on the pharmacy support staff role, you will see how you encourage individuals to become involved through health promotion activities and signposting to organisations that can provide support to the individual.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Be able to communicate effectively within pharmacy services	1.1	Describe the main purposes of communication with individuals within pharmacy services
		1.2	Describe the barriers to effective communication you may face within a pharmacy support staff role
		1.3	Demonstrate listening to and communicating effectively with users of the pharmacy services using a range of techniques to determine their needs and to reduce barriers
		1.4	Adapt information and communication style to meet the needs of different individuals
		1.5	Apply the principles of information governance and maintain confidentiality
		1.6	Demonstrate how to handle information in line with local and national policies
2	Understand person-centred care and support	2.1	Outline the principles of person-centred care and support, (even when the patient is not present)
		2.2	Demonstrate how to apply the principles of person-centred care within own role
		2.3	Apply the principles of consent appropriate to your role
		2.4	Describe the importance of treating individuals as valuable and unique
		2.5	Demonstrate how to promote and advocate equality, diversity and inclusion
3	Understand the role of pharmacy support staff in promoting	3.1	Outline the relationship between lifestyle and healthy living
		3.2	Describe how to get individuals actively involved in their own health and care
		3.3	Describe the impact of health inequalities on health, well-being and lifestyle in different parts of society

Learning outcomes		Assessment criteria	
	healthy lifestyles	3.4	Demonstrate promotion of healthy lifestyle programmes to individuals
		3.5	Outline the organisations that can support individual wellbeing
4	Understand the roles and responsibilities of pharmacy support staff in relation to safeguarding individuals	4.1	Define Safeguarding
		4.2	Describe how to recognise safeguarding concerns
		4.3	Explain how to raise and act upon safeguarding concerns

Unit content

What needs to be learned
Learning outcome 1: Be able to communicate effectively within pharmacy services
1A Main purpose of communication: gaining consent, involving others, involving other professionals, supporting others, enabling others, listening and understanding, give information to individuals and other professionals, advise on pharmacy related matters, obtain information from individuals and other professionals, adapt information for individuals and other professionals,
1B Barriers to effective communication: verbal vs non-verbal, environmental, disabilities, learning difficulties, social factors, language and cultural factors, religious beliefs, emotional, cognitive physical
1C Techniques: listening techniques, questioning techniques, verbal and non-verbal communication, clear speech, age appropriate language, formal and informal language
1D Reduce barriers: use of translation services, induction loops or T-loops, braille, communication in different formats such as written and verbal, adapt information when required to meet needs of the individual
1E Individuals: patients, carers, other members of the pharmacy and healthcare team, other health and social care staff
1F Information Governance and Confidentiality: legislation relating to confidentiality and data protection, such as Data Protection Act 2018 (ensure confidentiality of personal information). General Data Protection Regulations (GDPR) 2018 (protection of EU citizen's data, data can only be shared if lawful or consent is given), Caldicott principles, Duty of Candour, Information Governance and Freedom of information Act. Local policies and procedures, processing of information relating to patients, employees and corporate, record and store information securely to protect health and safety of individuals, ensure accurate information is passed on to the right people, protect individual rights, use of relevant systems in pharmacy practice, such as medicine ordering systems, controlled drug registers and to maintain security of patient records including IT systems and resources, values and restrictions of the use of social media relating to pharmacy and customers, escalate to line manager or Pharmacist if information is not secure. Restrictions of the use of social media; confidential information must not be shared, limits audience (certain groups may not use social media), can portray a negative reputation, information can quickly become out of date, boundaries can become blurred between personal and professional use. Values of the use of social media; allows for updates to be

shared quickly, allows for targeting of certain audiences, allows for collaboration between peers, colleagues and the public, can portray a positive reputation

1G Maintain confidentiality: secure storage of information, password-protected computers and files, monitor who has access to information relating to patients, individuals, employees and corporate, only disclose information when appropriate to do so

Learning outcome 2: Understand person-centred care and support

2A Person-centred care (even when person is not present): respecting diversity, respect for values, preferences and needs, listening to the individual, providing information and advice, involvement of individual, carers and key people in decisions about their care, confidentiality, compassion. Giving choice; right to make choices, importance of individual empowerment, not allowing personal views to influence individuals' decision-making, empowering individuals to make informed choices, respecting individuals' choices and empowering and supporting individuals to question or challenge decisions concerning them that are made by others.

2B Principles of consent: valid consent, when it is required, how it can be obtained, respecting individuals' choices, engaging individuals more effectively in their treatment, giving individuals access to appropriate information. Importance of gaining consent; ensures individuals have access to appropriate information, consequences (benefits, risks and alternatives) are discussed with individuals and understood, individuals understand the choices being given to them, legal requirement, individuals are able to provide authority, choices are respected, allows individuals to more effectively engage in their treatment and extra support is required for individuals with limited capacity.

2C Treating individuals as valuable: confidentiality, individuality, privacy, independence; dignity; respect individual's choices, partnership, care, compassion, courage, communication, tailoring information to individuals' needs, competence, gain trust, individual's right to make choices about their care, empower individuals to make informed choices, support individuals to question or challenge decisions made by others about their care

2D Equality, diversity and inclusion: legislation, local and national policies and procedures; awareness of who to contact in the health service

Learning outcome 3: Understand the role of pharmacy support staff in promoting healthy lifestyles

3A Lifestyle: diet, physical activity, smoking, substance misuse, recreation, risky behaviour, use of alcohol, diabetes awareness, heart health, sleep hygiene, correct use of medicines and medicinal products, mental health awareness

3B Actively involved: providing information and guidance, respecting choice, discussions with individuals, listening to concerns, signposting to support groups, charities and healthcare professionals. Reasons for getting people actively involved in their own health and care such as; people can take responsibility for their own health and care (ensuring they take their medication properly), physical benefits, emotional benefits, increased independence, autonomy and wellbeing and empowering individuals

3C Health inequalities: differences in health status, distribution of different health resources between different population groups

3D Different parts of society: socio-economic status, deprivation, low income, unemployment, protected characteristics, vulnerable groups of society or 'inclusion health' groups, location, impact of health inequalities; genetic predisposition and variation in available care due to location

3E Organisations: Public Health England, national and local support organisations, Diabetes UK, British Heart Foundation, Macmillan Cancer Support, rehabilitation clinics, counselling services, smoking cessation clinics, diabetes clinics, local groups, GP surgeries such as district nursing support, National Institute for Health and Care Excellence (NICE)

Learning outcome 4: Understand the roles and responsibilities of pharmacy support staff in relation to safeguarding individuals

4A Safeguarding: Working Together to Safeguard Children 2018, current Care Act Statutory Guidance, whistleblowing

4B Recognise safeguarding concerns: signs and symptoms; behaviours, procedures for referral, aware of who to contact in the health service, social services or the police in the event of a safeguarding concern

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources, e.g. *Safeguarding Adults and the Law*.

Assessment

This section must be read in conjunction with *Section 8 Assessment*.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning Outcome 1: Be able to communicate effectively within pharmacy services

An example of a suitable assignment to cover this learning outcome could be an information booklet for new staff outlining the main purposes for communication within pharmacy, the barriers they may encounter and methods to overcome these giving some examples to demonstrate this. The booklet should also describe the legislation and policies relating to information governance and explain how these are applied giving examples.

To satisfy the assessment criteria for this learning outcome, learners will, in their own words:

- 1 Describe the main purposes of communication with individuals within pharmacy services (A.C.1.1)
- 2 Describe **four** barriers to effective communication you may face within a pharmacy support staff role (A.C.1.2)

Assessment Criteria 1.3, 1.4, 1.5 and 1.6 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Learning Outcome 2: Understand person-centred care and support

An example of a suitable assignment to cover this learning outcome could be a poster with a presentation which can be displayed in the work area. The poster and presentation would need to outline the principles of consent and person centre care. It would also include the importance of treating individuals as valuable and unique and how to promote and advocate equality, diversity and inclusion. The presentation can be recorded and submitted as evidence.

To satisfy the assessment criteria for this learning outcome, learners will, in their own words:

- 1 Outline the principles of person-centred care and support, (even when the patient is not present). (A.C.2.1)
- 2 Explain the principles of consent and how these are applied (A.C.2.3)
- 3 Describe the importance of treating individuals as valuable and unique (A.C.2.4)

Assessment criteria 2.2 and 2.5 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Learning Outcome 3: Understand the role of pharmacy support staff in promoting healthy lifestyles

An example of a suitable assignment to cover this learning outcome could be a staff information booklet that outlines the relationship between lifestyle and healthy living. It would need to include the importance of individuals being actively involved in their own health and care and outline organisations that can provide support. It should also cover how health inequalities affect different parts of society.

To satisfy the assessment criteria for this learning outcome, learners will, in their own words:

- 1 Outline the relationship between lifestyle and healthy living. Include **three** examples of lifestyle to illustrate this (A.C.3.1)
- 2 Describe the importance of getting individuals actively involved in their own health and care, giving **three** examples of how they can do this (A.C.3.2)
- 3 Describe the impact of health inequalities on health, well-being and lifestyle in different parts of society (A.C.3.3)
- 4 Outline **three** organisations that can support individual wellbeing (A.C.3.5)

Assessment criterion 3.4 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Learning outcome 4: Understand the role and responsibilities of pharmacy support staff in relation to safeguarding individuals

An example of a suitable assignment to cover this learning outcome could be a short question and answer paper, assessing the learners' understanding of the responsibilities of their role in relation to safeguarding individuals. The question and answer paper should be written to generate a recognised definition of safeguarding and should assess the following three main areas:

- safeguarding – refer to: Working together to safeguard children 2018; current Care Act, Statutory Guidance; whistleblowing
- recognise safeguarding concerns – signs and symptoms; behaviours
- aware of who to contact in the health service, social services or the police in the event of a safeguarding concern

To satisfy the assessment criteria for this learning outcome, learners will, in their own words:

- 1 Specify exactly the meaning of safeguarding, using correct terminology and referring to Working together to safeguard children 2018, the current Care Act Statutory Guidance and whistleblowing (AC4.1)
- 2 Describe how to recognise safeguarding concerns, referring to signs, symptoms and behaviours (AC4.2)
- 3 Explain how to raise and act upon process for concerns about safeguarding (A.C.4.3)

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

Unit 2: Principles of Health and Safety for Pharmacy Support Staff

Level:	2
Unit type:	Mandatory
Credit value:	3
Guided learning hours:	15

Unit introduction

The aim of this unit is to give learners an understanding of health and safety requirements in relation to the pharmacy support staff role. The learning from this unit should be used to underpin practice within other units and will be assessed holistically.

This unit will develop your knowledge and understanding of health and safety within a pharmacy and how this applies to your role as pharmacy support staff. You will consider your own responsibilities in relation to health and safety in the workplace, including relevant health and safety legislation and the main health and safety responsibilities of both yourself and your employer, and others within your workplace. Within your workplace practices, you will be able to demonstrate how you apply health and safety legislation and policies and procedures.

You will develop an understanding of risk management, through the process of risk assessment in relation to your workplace practices. You will also develop your knowledge and understanding of workplace procedures for responding to accidents and emergencies when they happen, and the responsibilities relating to your own role in responding to accidents and emergencies within the workplace.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Understand responsibilities relating to health and safety in the workplace	1.1	Outline the legislation relating to health and safety in pharmacy services
		1.2	Identify the main health and safety responsibilities for: <ul style="list-style-type: none"> • pharmacy support staff • employer • others in the workplace
		1.3	Demonstrate the application of health and safety legislation, policies and procedures in relation to workplace practices
2	Understand risk management	2.1	Outline the process of risk assessment in the workplace
		2.2	Explain the use of health and safety risk assessment in relation to workplace practices
3	Understand procedures for responding to accidents and emergencies	3.1	Describe the procedures for dealing with accidents and emergencies in own workplace
		3.2	Outline the responsibilities of pharmacy support staff in responding to accidents and emergencies

Unit content

What needs to be learned
Learning outcome 1: Understand responsibilities relating to health and safety in the workplace
1A Legislation: Health and Safety at Work Act 1974, manual handling, disposal of pharmaceutical waste, Control of Substances Hazardous to Health (COSHH), workplace injury, workplace ill health, Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR), Health and Safety (First Aid) Regulations 1981
1B Health and Safety responsibilities: the roles and responsibilities described in the relevant legislation, policies, regulatory requirements, codes of conduct and Standard Operation Procedures (SOPs)
1C Application: of legislation, policies, regulatory requirements (GPhC), Standard Operating Procedures (SOPs), Code of Conduct and any other organisational requirements, to ensure best interests of individuals and prevent harm to self and other
Learning outcome 2: Understand risk management
2A Risk assessment: aspects of the workplace which can cause harm (hazards), who is at risk of being harmed, evaluation of risk (e.g. risk rating), controls measures, recording risk and reviewing risk, Health and Safety Executive (HSE) guide to risk assessment, accident recording to identify common occurrences and informs assessment to prevent similar accidents occurring, Control of Substances Hazardous to Health (COSHH) assessments. Identifying risks and hazards; Five steps of risk assessment, manual handling risk assessment ; TILE, Error reporting, Waste disposal, environmental assessment
2B Workplace practices: manual handling, handling hazardous substances, workstations, disposal of pharmaceutical waste, pharmacy error reporting and near miss reporting, warning labels on medicines, fridge temperature checks to prevent risk of dropping below or above temperature

Learning outcome 3: Understand procedures for responding to accidents and emergencies

3A Accidents and emergencies: spillages of pharmaceutical products/waste, accidental release of substances hazardous to health, medical conditions/emergencies, sudden illness; slips, trips, falls; minor injury, bleeding, anaphylaxis, seizure, fire

3B Responsibilities of pharmacy support staff: follow organisational procedures following accidents or emergencies, work within limitations of own role and refer to others outside of limitations, ensure safety of self and others, alert emergency services as appropriate, refer to named First Aider within the workplace, follow spillage guidelines (COSHH), accurate accident reporting

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need internet access to obtain copies of relevant legislation, e.g. Health and Safety Executive (HSE) website.

Assessment

This section must be read in conjunction with *Section 8 Assessment*.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning outcome 1 Understand responsibilities relating to health and safety in the workplace

An example of a suitable assignment to cover this learning outcome could be a short question and answer paper, assessing the learner's understanding of the responsibilities of their role, in relation to health and safety in the workplace.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide a brief overview of relevant Health & Safety legislation, highlighting the main points (AC 1.1)
- 2 List the main responsibilities of employees and employers (AC 1.2)

Another suitable assignment to cover assessment criteria 1.1 and 1.2 could be a professional discussion.

Assessment Criterion 1.3 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Learning outcome 2 Understand risk management

An example of a suitable assignment to cover this learning outcome could be a short question and answer paper, assessing the learner's understanding of risk management in their workplace, the process of risk assessment and the use of health and safety risk assessment in relation to workplace practices.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Outline the risk assessment process. The overview should include; aspects of the workplace which can cause harm (hazards), who is at risk of being harmed, evaluation of risk (e.g. risk rating), controls measures, recording risk and reviewing risk (AC 2.1).
- 2 Explain how risk assessments are used to manage risks related to manual handling; handling hazardous substances; workstations and disposal of pharmaceutical waste (AC 2.2).

Another suitable assignment to cover assessment criteria 2.1 and 2.2 could be a professional discussion.

Learning outcome 3 Understand procedures for responding to accidents and emergencies

An example of a suitable assignment to cover this learning outcome could be a short question and answer paper, assessing the learner's understanding of procedures for dealing with accidents and emergencies in their own workplace and the responsibilities of their own role as pharmacy support staff for responding to accidents and emergencies in the workplace.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Describe procedures for dealing with spillages of pharmaceutical products/waste, medical conditions/emergencies, sudden illness; slips, trips, falls and minor injury. The description should highlight the main points. (AC 3.1)
- 2 Outline a list of pharmacy support staff responsibilities when dealing with accidents and emergencies (AC 3.2)

Another suitable assignment to cover assessment criteria 3.1 and 3.2 could be a professional discussion.

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

Unit 3: Effective Teamwork within Pharmacy Services

Level:	2
Unit type:	Mandatory
Credit value:	3
Guided learning hours:	15

Unit introduction

The aim of this unit is to enable learners to develop their knowledge and understanding of effective teamwork and how their role supports this. The unit covers the principles behind effective teamwork and how these impact on users of the pharmacy service. The unit also covers conflict resolution and develops learners skills in establishing effective working relationships with all members of their own pharmacy and the wider healthcare team.

In this unit you will develop your understanding of your own role, responsibilities and limitations and the roles and responsibilities of others within the pharmacy and wider healthcare team. You will show how you work within the limits of your own knowledge and skills and how you refer individuals or issues where appropriate to another member of the team. You will develop your knowledge of professional standards, current legislation and organisational procedures that apply to teamwork.

You will explore the principles behind effective team working and how these impact on the team as a whole. You will learn how to work with others to ensure the patients' best interests are met. You will explore how to resolve difficult situations both with other team members whilst respecting others opinion. You will have the opportunity to further develop your communication skills and demonstrate communicating effectively with both your team and service users.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Understand different roles and responsibilities within the pharmacy and healthcare team	1.1	Explain own roles and responsibilities as pharmacy support staff
		1.2	Explain the roles and responsibilities of the members within the: <ul style="list-style-type: none"> • wider pharmacy team • wider healthcare team
		1.3	Demonstrate working within the limits of your knowledge and skills
		1.4	Demonstrate referral of individuals or issues as appropriate to another member of the team
2	Understand the legal and ethical requirements relevant to teamwork	2.1	Identify all the professional standards that relate to the pharmacy team
		2.2	Describe current legislation and organisational procedures relating to teamwork
		2.3	Describe current legislation and organisational procedures relating to equality and diversity within team working
3	Understand the principles of effective teamwork	3.1	Identify the key features of effective teamwork
		3.2	Explain how styles of interaction impact on the team
		3.3	Explain how your role contributes to the team activities
4	Understand the importance of effective teamwork on pharmacy services	4.1	Describe how to work in the patient's best interest with people within and outside your organisation
		4.2	Explain the impact of effective teamwork on <ul style="list-style-type: none"> • the patient/carer • other members of staff • on the organisation

Learning outcomes		Assessment criteria	
		4.3	Explain how to have difficult conversations and resolve conflict within the team whilst respecting others' opinions
		4.4	Describe the organisational policy and procedure for handling complaints
5	Be able to establish effective working relationships with all members within pharmacy services	5.1	Demonstrate how to communicate effectively with users of pharmacy services within: <ul style="list-style-type: none"> • own pharmacy team • wider healthcare team
		5.2	Demonstrate working effectively as a member of the pharmacy/ wider healthcare team
		5.3	Demonstrate trust and respect for individual, members of the pharmacy team and health professionals

Unit content

What needs to be learned
Learning outcome 1: Understand different roles and responsibilities with the pharmacy and healthcare team
1A Roles and Responsibilities: Registered and non-registered staff groups, Pharmacy Support Staff, Pharmacy Technician, Pharmacist, Responsible Pharmacist, healthcare assistants, nurses, midwives, job descriptions, limitations and accountability of role, GPhC pharmacy role definitions and educational requirements
Learning outcome 2: Understand the legal and ethical requirements relevant to teamwork
2A Professional Standards: GPhC Standards for Pharmacy Professionals, GPhC Standards for Registered Pharmacies, GPhC requirements for the education and training of pharmacy support staff, professional leadership bodies, General Medical Council (GMC)
2B Current legislation: Data Protection, Equality and Diversity, Freedom of Information
2C Organisational procedures: Standard Operating Procedures (SOPs), organisational policies and procedures relating to teamwork and equality and diversity in the workplace, lone working, incorporate relevant legislation, ensure patient safety, consistent standard of working, safe method of working
Learning outcome 3: Understand the principles of effective teamwork
3A Effective teamwork: effective communication, supporting others, resolve conflict, intended outcomes, understand own role and that of others in the pharmacy and healthcare, giving and receiving feedback, supporting the team for development of others
3B Styles of interaction: Belbin team roles, Tuckman theory, Johari window
Learning outcome 4: Understand the importance of effective team work on pharmacy services
4A How to work in the patient's best interest: understand patients' preferences to suit individual needs, ensure effective teamwork and communication to maintain patients' interests, resolve conflict, ensure patients receive the best care, work across multi-disciplinary teams and multiple organisations where necessary, resolve queries in a timely manner and ensure cost effectiveness of treatment e.g. medical exemption or pre-payment card
4B Impact: individual, patient, customer satisfaction, reputation of department and organisation, time saving, cost effectiveness, improved relationships, build good working relationships, improves teamwork, builds individual, patient, customer trust

4C Resolve conflict: conflict resolution policies for organisation, complaint procedures for organisation and professional bodies, Health Ombudsman, General Pharmaceutical Council (GPhC), respect differences of opinion and points of view, agree to disagree

Learning outcome 5: Be able to establish effective working relationships with all members within pharmacy services

5A Working effectively: use of effective communication and listening techniques, refer issues and seek help and guidance from other members of the team when unsure or outside scope of role, behave in a professional manner towards other members of the team, recognise roles and responsibilities of the pharmacy and wider healthcare team and work within limitations of own role, accountability of own role, follow standards and codes of conduct, raise concerns or if things go wrong, reliability and consistency in own role

5B Trust and respect: show empathy and value those you work with, recognise individuals' values and beliefs, give regard to diversity and confidentiality of individuals and members of the pharmacy and healthcare team to build trust, nature of professional respect, value contributions and responsibilities of others you work with, treat others fairly and equally, recognise expertise of and help from others, build trust with individuals and other team members by being reliable and consistent, act with integrity and fair conduct

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books and electronic resources.

Assessment

This section must be read in conjunction with *Section 8 Assessment*.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning outcome 1 Understand different roles and responsibilities within the pharmacy and healthcare team

An example of a suitable assignment to cover this learning outcome could be a poster, accompanied by a presentation, to be displayed in the work area as a reference tool, clearly explaining the roles and responsibilities of each team member. The presentation can be recorded and submitted as evidence.

To satisfy the assessment criteria for this learning outcome, learners will, in their own words:

- 1 Explain their own roles and responsibilities as Pharmacy Support Staff (A.C.1.1)
- 2 Explain the roles and responsibilities of the members within both the wider Pharmacy team and the wider healthcare (A.C.1.2)

Assessment criteria 1.3 and 1.4 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Learning outcome 2 Understand the legal and ethical requirements relevant to teamwork

An example of a suitable assignment to cover this learning outcome could be a training booklet for new staff which covers the professional standards that relate to the pharmacy team. It should also describe the legislation and organisational procedures that relates to teamwork and equality and diversity.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Identify **all** the professional standards that relate to the pharmacy team (A.C.2.1)
- 2 Describe, in their own words, **at least three** examples of current legislation and organisational procedures relating to teamwork (A.C.2.2)
- 3 Describe, in their own words, current legislation and organisational procedures relating to equality and diversity within team working (A.C.2.3)

Learning outcome 3 Understand the principles of effective teamwork

An example of a suitable assignment to cover this learning outcome could be a pocket guide for staff identifying and explaining the principles of effective teamwork and how each team member can impact on and contribute to the team.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Identify **at least four** key features of effective teamwork (A.C.3.1)
- 2 Explain, in their own words, how **two** styles of interaction impact on the team (A.C.3.2)
- 3 Explain, in their own words, how your role contributes to the team activities (A.C.3.3)

Learning outcome 4 Understand the importance of effective teamwork on pharmacy services

An example of a suitable assignment to cover this learning outcome could be a powerpoint presentation to be used within a pharmacy team training session. The presentation would need to cover how to work in the patients' best interest at all times, and explain the impact of effective teamwork on patients, staff and the organisation. The presentation should also cover the procedures for handling complaints and explain how to resolve conflict. There is no need for learners to deliver the presentation. The presentation can be recorded and submitted as evidence.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Describe, in their own words, how to work in the patient's best interest with people within and outside your organisation (A.C.4.1)
- 2 Explain the impact of effective teamwork on each of the following:
 - The patient/carer
 - Other members of staff
 - On the organisation (A.C.4.2)
- 3 Explain how to have difficult conversations and **two** ways to resolve conflict within the team whilst respecting others' opinions (A.C.4.3)
- 4 Describe, in their own words, the organisational policy and procedure for handling complaints (A.C.4.4)

Learning outcome 5 Be able to establish effective working relationships with all members within pharmacy services covers the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

Unit 4: Personal Development for Pharmacy Support Staff

Level:	2
Unit type:	Mandatory
Credit value:	4
Guided learning hours:	20

Unit introduction

This aim of this unit is to provide learners with knowledge of how pharmacy services are regulated and enable them to understand how legislation, regulations and standards impact their role. The unit will also enable learners to demonstrate an understanding of their own limitations and how to reflect on and develop their own practice.

This unit will develop your knowledge and understanding of how your workplace is regulated and importantly the role of the General Pharmaceutical Council and how this relates to your own role as pharmacy support staff. You will understand the importance of adhering to pharmacy legislation, regulations and agreed standards of practice and be able to demonstrate compliance with these within your own role.

You will develop an understanding of how to examine your own performance within your role, knowing the limitations of the role and be able to recognise and work within the limitations of your own knowledge and skills, identifying ways to seek appropriate support when needed.

You will develop an understanding of continuing personal development within your role as pharmacy support staff and the importance of reflection to identify development needs. You will be able to work with others to develop a personal development plan and take part in appropriate development activities.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Understand how pharmacy services are regulated	1.1	Outline the role of the General Pharmaceutical Council and the relevance to own role
		1.2	Describe the importance of professional standards that govern the delivery of pharmacy services as applicable to own role
		1.3	Explain the importance of adhering to pharmacy legislation, regulations and agreed standards of practice
		1.4	Demonstrate compliance with relevant pharmacy legislation, regulations and agreed standards of practice
2	Understand how to examine own performance	2.1	Describe limitations of own role in relation to: <ul style="list-style-type: none"> ▪ pharmacy legislation and regulations ▪ agreed standards of practice ▪ knowledge and skills
		2.2	Recognise and work within limitations of own knowledge and skills
		2.3	Identify ways of seeking appropriate support in the workplace
3	Understand how to reflect on and develop own practice	3.1	Explain the importance of continuing personal development for pharmacy support staff
		3.2	Explain the importance of reflection to identify development needs and support improved practice
		3.3	Work with others to develop a personal development plan and participate in appraisal and review

Learning outcomes		Assessment criteria	
		3.4	Participate in appropriate development activities to maintain and develop skills and knowledge
		3.5	Describe how to use feedback and evidence from reflection and appraisal to improve own practice

Unit content

What needs to be learned
<p>Learning outcome 1: Understand how pharmacy services are regulated</p> <p>1A Role: public protection; registration of pharmacy premises; registration of pharmacists and pharmacy technicians, sets standards for practice, regulates fitness for practice, General Pharmaceutical Requirements (GPhC) for the education and training of pharmacy support staff</p> <p>1B Professional standards: General Pharmaceutical Council professional standards and guidance, GPhC Standards for Pharmacy Professionals, GPhC Standards for Registered Pharmacies</p> <p>1C Pharmacy legislation: The Medicines Act 1968, Human Medicines Regulations 2012; Falsified Medicines Legislation; Medicines and Healthcare products Regulatory Agency (MHRA), e.g. licensing, legal categorisation</p> <p>1D Regulations: Responsible Pharmacist regulations, MHRA</p> <p>1E Agreed standards of practice: may include, organisational policies, Standard Operating Procedures (SOPs), organisational codes of conduct, job description and employment contract</p>
<p>Learning outcome 2: Understand how to examine own performance</p> <p>2A Pharmacy legislation: The Medicines Act 1968, Human Medicines Regulations 2012, Falsified Medicines Legislation, Medicines and Healthcare products Regulatory Agency (MHRA), e.g. licensing, legal categorisation</p> <p>2B Regulations: Responsible Pharmacist regulations, MHRA</p> <p>2C Agreed standards of practice: organisational policies, Standard Operating procedures (SOPs), organisational codes of conduct, job description and employment contract. Rationale behind Standard Operating Procedures; incorporates relevant legislation; to ensure patient safety; consistent standard of working; safe method of working. Requirements of Standard Operating Procedures; defines limitations of roles in the pharmacy, incorporate GPhC Standards for Registered Pharmacies</p> <p>2D Limitations of own knowledge and skills: individual limitations related to training and competence, recognising and raising concerns within own limitations, recognising strengths and weakness</p> <p>2E Support in the workplace: may include referral to others, e.g. another member of the team, GP, healthcare worker, manufacturer, or seeking advice and guidance to resolve a situation within own limitations, raising concerns even when not easy to do using appropriate systems. Where to go: Line managers; anything outside scope of role, absences. Other team members; pharmacy services assistant, pharmacy technician, pharmacist); Human resources (external to the pharmacy department, contact by telephone or online); wages, grievances, disciplinaries, annual leave,</p>

employment contract, changes in hours; Tutors/mentors; Learning & development and training opportunities; Training departments and providers; details of courses available, how to register onto courses, certification queries; Professional regulators (General Pharmaceutical Council (GPhC)); raise concerns regarding colleagues or premises, report incidents which have occurred at work, access standards and educational requirements; Unions (Unison); disciplinary, conflicts, wages; Parliamentary and Health Service Ombudsman (contact by telephone or online); raise complaints that have not been dealt with by the NHS or other UK government departments or public organisations

Learning outcome 3: Understand how to reflect on and develop own practice

3A Continuing personal development: maintaining up to date knowledge of pharmacy processes and practice; opportunity to address own training and development needs; improves confidence; maintains competence, maintain up to date knowledge of legislation and regulation, maintain and improve own competence, maintain and expand own interest in the role, supports progression, improves productivity and job satisfaction

3B Reflection: may include reflection on action and reflection in action, identify learning needs and training opportunities, using SWOT analysis or feedback from others, appraisals, identify and learn from mistakes, identify strengths and weaknesses, identify achievement of personal goals

3C Development needs: learning needs; interests; development opportunities

3D Others: may include peers; senior colleagues; managers

3E Development activities: in-house training; mandatory organisational training; online learning; shadowing peers and colleagues

3F Feedback: feedback could be formal, e.g. performance review or team meeting, feedback from line manager or informal, e.g. discussion with peer or colleague. Feedback could also be from service users, use of constructive feedback

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need internet access to obtain copies of relevant standards and legislation e.g. General Pharmaceutical Council website.

Assessment

This section must be read in conjunction with Section 8 Assessment.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning outcome 1 Understand how pharmacy services are regulated

An example of a suitable assignment to cover this learning outcome could be a short question and answer paper, assessing the learner's understanding of how pharmacy services are regulated.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Give a brief overview of the General Pharmaceutical Council's (GPhC) role, highlighting the main points. An explanation of how the GPhC role relates to the pharmacy support worker role (AC 1.1)
- 2 Provide a description of the importance of professional standards and how they relate to the pharmacy support worker role (AC 1.2)

- 3 Provide an explanation of the importance of following relevant legislation, regulations and agreed standards of practice (AC 1.3)

Another suitable assignment to cover assessment criteria 1.1, 1.2 and 1.3 could be a professional discussion.

Assessment criterion 1.4 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Learning outcome 2 Understand how to examine own performance

An example of a suitable assignment to cover this learning outcome could be a short question and answer paper, assessing the learner's understanding of how to examine their own performance, describing the limitations of their own role and identifying ways of seeking support.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide a description of a pharmacy support workers limitations, in accordance with pharmacy legislation, regulations and agreed standards of practice. An understanding of limitations which are specific to an individual's knowledge and skills (AC 2.1)
- 2 Give a list of options for obtaining support in the workplace (AC 2.3)

Another suitable assignment to cover assessment criteria 2.1, 2.2 and 2.3 could be a professional discussion.

Assessment criterion 2.2 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor

Learning outcome 3 Understand how to reflect on and develop own practice

An example of a suitable assignment to cover this learning outcome could be a short question and answer paper, assessing the learner's understanding of how to reflect on and develop their own practice.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide an explanation of the importance of continuing professional development, to include the risks of not maintaining knowledge and skills (AC 3.1)
- 2 Provide an explanation of the importance of reflection, to inform development needs and improve practice (AC 3.2)
- 3 Give a description of how to improve practice, using feedback, reflection and appraisal (AC 3.5)

Another suitable assignment to cover assessment criteria 3.1, 3.2 and 3.5 could be a professional discussion.

Assessment criteria 3.3 and 3.4 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

Unit 5: Dispensing and Supply of Prescribed Medicines and Medicinal Products

Level:	2
Unit type:	Optional
Credit value:	10
Guided learning hours:	70

Unit introduction

This unit aims to provide learners with the knowledge and understanding required to receive and process prescriptions. Learners will gain knowledge and skills in assembling medicines in preparation for dispensing prescription medicines safely and supplying prescribed medicines and medicinal products.

This unit introduces you to legislation associated with receiving, processing, assembling, dispensing and supplying prescribed medicines and products. You will develop an understanding of the importance of standard operating procedures (SOPs) and be required to demonstrate this understanding by using SOPs to receive and process prescriptions; identifying issues that may affect how patients take their medicines. You will also learn about different types of prescriptions, prescription charges, exemptions and transactions when receiving and processing prescriptions. Roles and responsibilities of the pharmacy team in supplying prescriptions will also be explored.

The unit also covers assembling, dispensing and supplying medicines, accurately recording information of dispensed medicines and products; using this knowledge to identify different forms and doses of medication and routes of administration. You will then show your skills in undertaking in process accuracy checks and accurate pharmacy calculations.

This unit enables you to develop knowledge of advising on prescribed medicines and products, including their storage and disposal and knowing when to refer to the appropriate person or seek advice if required, outside of your own competence.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Understand legislation and regulatory requirements for receipt, assembling, dispensing and supply of prescribed medicines and products	1.1	Outline legislation, regulatory requirements and current organisational guidelines that applies to: <ul style="list-style-type: none"> • Receiving and processing prescriptions • Assembling medicines and products • Dispensing medicines and products • Supplying medicines and products
		1.2	Explain the importance of following standard operating procedures (SOPs) in relation to: <ul style="list-style-type: none"> • Receiving and processing prescriptions • Assembling medicines and products • Dispensing medicines and products • Supplying medicines and products
2	Be able to receive and process prescriptions	2.1	Describe the different types of prescriptions
		2.2	Describe the roles and responsibilities of staff for receiving and processing prescriptions
		2.3	Demonstrate how to receive and process prescriptions
3	Be able to assemble and dispense prescribed items	3.1	Identify different forms and doses of medication and routes of administration
		3.2	Identify any factors that may affect how medicines are taken
		3.3	Identify any issues relating to the assembling and dispensing of medicines and products and take necessary action
		3.4	Demonstrate how to assemble and label prescribed medicines and products relevant to own role
		3.5	Demonstrate how to accurately dispense prescribed medicines and products

Learning outcomes		Assessment criteria	
4	Be able to undertake an in-process accuracy check on prescribed medicines and products safely	4.1	Explain the importance of accurately recording information relating to dispensing and supply of medicines and products
		4.2	Perform an in-process accuracy check on the dispensed medicines and products
		4.3	Explain how to accurately perform dispensing calculations in accordance with the prescription
5	Be able to supply prescribed medicines and products safely	5.1	Identify any issues relating to supply of medicines and products and take necessary action
		5.2	Describe any additional materials and consumables that may be required when supplying prescribed medicines
		5.3	Describe the procedures and roles and responsibilities of staff for supplying prescription medicines and products
		5.4	Accurately supply medicines and products
		5.5	Provide appropriate advice when authorised on supplied medicines and products

Unit content

What needs to be learned

Learning outcome 1: Understand legislation and regulatory requirements for receipt, assembling, dispensing and supply of prescribed medicines and products

1A Legal and current organisational policies and guidelines: may include that which is relevant to: receiving, processing, assembling, dispensing and supplying medicines, assembling and issuing licensed, unlicensed and clinical trials medication, data protection, equality and diversity, health and safety, ethical and legal requirements; clinical trial policies

1B Regulatory: General Pharmaceutical Council Professional Standards, current National Institute for Health and Care Excellence (NICE) guidance, Medicines Health Products and Regulatory Agency (MHRA) drug alerts and recalls, Human Medicines Regulations 2012, Medicines Act 1968, Misuse of Drugs Act 1971 (controlled drugs (amendment) order 2018), Control of Substances Hazardous to Health Regulations (COSHH) 2002, Care Quality Commission

1C Standard Operating Procedures: SOPs for receiving, processing, assembling, dispensing and supplying medicines, risk management, incident management and error reporting systems, safe storage of medicines, handling of different drugs, automated ordering, use of technology, use of personal protective equipment (PPE), handling cytotoxic medicines, reconstitutions, labelling requirements

Learning outcome 2: Be able to receive and process prescriptions

2A Different types of prescriptions: paper and electronic, prescriptions for controlled drugs, patient group direction, different prescribers such as general practitioners; pharmacist prescribers; veterinary; dental; nursing prescribers, hospital-only scripts, clinical trial scripts

2B Roles and responsibilities: take action when a prescription is not valid, limitations of own role and competence, referral process, seeking authority, liability, negligence, duty of care

2C Receive and process prescriptions: dispensary records: purpose; type of records; function of records; patient identification; use of computer systems; paper and electronic records including patient medication records (PMRs); checking prescription validity, error recording, details required on prescriptions, payment methods, exemptions, refunds, prepayment certificates, prescription charge, receiving the prescription

Learning outcome 3: Be able to assemble and dispense prescribed items

3A Forms and doses: brand and generic names, abbreviations, conventions, different strengths, doses and quantities, types of formulations, reconstitution, liquids, tablets, capsules, granules, powder, injections, infusions, patches, implants, drops, topical medicines, suppositories, enemas, pessaries, vaginal tablets, inhalers, nasal sprays, nanograms, micrograms, milligrams, grams, minims, millilitres, puffs

3B Routes of administration: routes by which drugs are delivered to the body including oral, rectal, injectable, transdermal, inhaled, advantages and disadvantages of each route

3C Factors: dysphagia, dexterity, route of administration, age, disability, lifestyle, ethnicity, side effects, allergies, adverse drug reactions, dietary, patient weight, other medicines being taken, how the body metabolises the drug, conscious state

3D Issues: lack of stock, dispensing errors and near misses

3E Assemble and label: preparing the area, following SOP, prepare appropriate labelling, correct packaging, including containers e.g. child resistant containers, patient own packs, materials used, original packs, additional equipment e.g. oral syringes, patient information leaflets, spacer devices

3F Dispensing: following SOP, preparing assembled medicine, labelling medicine appropriately, send for final check with appropriate person, factors that influence dispensing; legislation, CQC inspection of monitoring of procedures and practices, feedback that informs change in procedures and practices

Learning Outcome 4: Be able to undertake an in-process accuracy check on prescribed medicines and products safely

4A Recording information: details that should be recorded and the reasons why these are important and the format to be used; records must be accurate and legible for use and audit purposes, impact on individual and the organisation

4B In-process accuracy check: confirm the validity of prescription, check that the correct item has been assembled and dispensed in the correct form and correct strength; check that the correct quantity has been assembled or arrangements made for further supply as indicated on the prescription; check the accuracy of the label including:

- individual's name
- drug name, form and strength
- quantity
- directions for use
- advisory and cautionary warnings
- expiry and storage instructions if applicable

check that the assembled and dispensed items are fit for purpose; check appropriate packaging has been used; check appropriate selection of medicine devices or sundry items to accompany the medicine or product; rectify any identified dispensing errors

4C Dispensing calculations: different weights and measures; volumes; percentages; ratios; formulae for dilutions; dosages and quantities for individuals based on: age, weight, surface area and blood volume; quantity of medicine based on number of prescribed doses and time intervals, reducing doses, increasing doses

Learning outcome 5: Be able to supply prescribed medicines and products safely

5A Issues with supplying medicines: prescribed medicines unavailable

5B Additional equipment: requirements when supplying prescribed medicines, e.g, oral syringes, patient information leaflets, spacer devices, infusion slips

5C Appropriate person: line manager, pharmacist, pharmacy technician, supervisor

5D Accurately supply: confirm prescription details, make appropriate accuracy supply checks, ensuring supply to right person and/or location

5E Appropriate advice: could be verbal, using patient information leaflets or additional instruction leaflets, using, storing and maintaining devices, using and storage of medication and possible side effects, disposal of medication

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals, electronic resources and apps, e.g. *BNF British National Formulary*.

Assessment

This section must be read in conjunction with *Section 8 Assessment*.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning outcome 1: Understand legislation and regulatory requirements for receipt, assembling, dispensing and supply of prescribed medicines and products

An example of a suitable assignment to cover this learning outcome could be an information booklet that outlines organisational policies and guidelines for receiving, processing, assembling, dispensing and supplying medicines in line with Standard Operating Procedures. The information booklet will need to include details of regulatory bodies that provide guidance on the legislation for dispensing and supplying prescribed medicines and products and the importance of adhering to Standard Operating Procedures.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide details of the current legislation and organisational policies/guidelines that apply to receiving, processing, assembling and dispensing medicines and products and the regulatory bodies that support this legislation (AC1.1).
- 2 Give reasons why it is important to follow Standard Operating Procedures in relation to receiving, processing, assembling, dispensing and supplying medicines and products, using examples of when Standards Operating Procedures would be used. (AC1.2).

Learning outcome 2: Be able to receive and process prescriptions

An example of a suitable assignment to cover this learning outcome could be a staff information booklet that outlines different type of prescriptions and the role of staff members in receiving and processing the prescriptions. The staff information booklet will need to include different types of prescriptions that may be received, details on the roles and responsibilities of those in the pharmacy team when receiving and processing prescriptions and a detailed explanation of organisational procedures for receiving and processing prescriptions in line with Standard Operating Procedures (SOPs).

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 give details of **at least three** types of prescription forms, giving reasons and examples to support the points made (AC.2.1).
- 2 provide details of the roles and responsibilities of staff for receiving prescriptions, giving reasons and examples to support the points made (AC.2.2).

Assessment criterion 2.3 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

For learning outcomes 3, 4 and 5, learners must evidence that they can correctly assemble and dispense 200 prescribed medicines and products, with no errors being made and self-checked consistently over a period of time in a range of circumstances.

Learning outcome 3: Be able to assemble and dispense prescribed items

An example of a suitable assignment to cover this learning outcome could be a reflective account of assembling and dispensing prescribed items in line with a Standard Operating Procedure (SOP). The learner will need to reflect on how they used a Standards Operating Procedure (SOP) to assemble and dispense a prescribed item. They will need to explain the processes for assembling and dispensing prescribed items, including how forms, doses of medicine and routes of administration are factors when labelling a prescribed medicine or product. They should also reflect on how they chose correct packaging, containers and additional equipment that may be required. This account should show how they have reflected on the processes followed to safely assemble and dispense against a Standard Operating Procedure (SOP).

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 provide details of **at least two** different forms and doses of medication and **at least two** routes of administration, giving reasons and examples to support the points made (AC.3.1).
- 2 provide details of factors that may affect how medication are taken, giving reasons and examples to support the points made (AC3.2).
- 3 provide details of issues relating to assembling and dispensing medicines and products, giving examples of necessary action to be taken to support the points made (AC3.3).

Assessment criteria 3.4 and 3.5 covers the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Learning outcome 4: Be able to undertake an in-process accuracy check on prescribed medicines and products safely

An example of a suitable assignment to cover this learning outcome could be a reflective account of safely undertaking an in process accuracy check on prescribed medicines and products, including accurately performing dispensing calculations. The learner will need to reflect on their own process for an in process check and explain the importance of accurately recording information. They should also reflect on

dispensing calculations to ensure accuracy when dispensing prescribed medicines and products. The account should show how they have reflected on their own process for an in process check to reduce the risk of dispensing errors occurring.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 give reasons why it is important to accurately record the supply of medicine and product information when dispensing, using examples to support the points made (AC4.1)
- 2 give a clear account of how to accurately perform dispensing calculations in accordance with the prescription, using their own words and including all the relevant information (AC4.3).

Assessment criterion 4.2 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Learning outcome 5: Be able to supply prescribed medicines and products safely

An example of a suitable assignment to cover this learning outcome could be a staff pocket guide for staff members on safely supplying prescribed medicines and products. The pocket guide will need to include details of issues relating to supplying medicines and products and any necessary action to be taken. It should also detail additional equipment required when supplying prescribed medicines and explain the roles and responsibilities of the pharmacy team for supplying medicines, giving reasons why accuracy is important.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 provide details of **at least two** issues relating to the supply of medicines and products and any necessary action taken, giving reasons and examples (AC5.1).
- 2 provide details of **at least three** additional materials or consumables that may be required when supplying prescribed medicines, giving reasons and examples to support the points made, giving reasons and examples (AC5.2).
- 3 give a clear account of the roles and responsibilities of staff when supplying prescription medicines, using their own words and including all the relevant information (AC5.3).

Assessment criteria 5.4 and 5.5 covers the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

Unit 6: Managing Pharmaceutical Stock

Level:	2
Unit type:	Optional
Credit value:	10
Guided learning hours:	70

Unit introduction

The aim of this unit is to provide learners with the knowledge, understanding and skills to manage pharmaceutical stock effectively. The unit covers pharmaceutical stock control requirements, including ordering and receiving stock from the correct supplier. The unit also covers maintenance and safe storage of stock and issuing stock.

In this unit you will develop your understanding of legislation, regulatory governance and Standard Operating Procedures that apply to the management of pharmaceutical stock.

You will explore pharmaceutical stock requirements that apply to ordering including, the impact of seasonal and regional requirements and learn how to receive pharmaceutical stock including dealing with discrepancies. You will explore the importance of maintaining pharmaceutical stock including, how to respond to drug alerts and recalls, safe handling and disposal of waste materials and how automation is used to control stock.

This unit also provides you with the opportunity to demonstrate how to assemble and issue stock. You will explore different forms of medicines and the importance of supplying appropriate quantities and consider special packaging and transportation requirements.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Understand governance requirements relating to managing pharmaceutical stock	1.1	Describe legal, regulatory and current organisational guidelines that apply to managing pharmaceutical stock
		1.2	Explain the importance of following Standard Operating Procedures in relation to managing pharmaceutical stock
		1.3	Explain the limitations of own role and when to refer to others
2	Understand pharmaceutical stock	2.1	Outline different types of drug formulations within pharmacy stock
		2.2	Describe the difference between branded and generic medicines
		2.3	Explain the importance of ensuring that stock is available to individuals
		2.4	Identify different sources and suppliers of stock
3	Be able to order pharmaceutical stock	3.1	Describe the order requirements for pharmaceutical stock
		3.2	Demonstrate how to accurately order pharmaceutical stock, using pharmacy IT systems and other IT resources, in accordance with legal requirements, organisational policies and Standard Operating Procedures , including: <ul style="list-style-type: none"> • Checking stock • Placing and Processing order • Maintaining documentation • Reporting and problems

Learning outcomes		Assessment criteria	
4	Be able to receive pharmaceutical stock	4.1	Explain the importance of referring to current drug alerts and recalls when receiving pharmaceutical stock
		4.2	Demonstrate the process for confirming receipt of pharmaceutical stock, using pharmacy IT systems, in accordance with legal requirements, organisational policies and Standard Operating Procedures
		4.3	Identify and take appropriate action to deal with discrepancies in relation to received pharmaceutical stock
5	Be able to maintain pharmaceutical stock	5.1	Explain the importance of monitoring and maintaining a safe, secure and clean working environment
		5.2	Describe the action to take when drug alerts or recalls are received
		5.3	Demonstrate how to store and maintain pharmaceutical stock correctly including: <ul style="list-style-type: none"> • Storage requirements • Stock rotation procedures • Checking expiry dates • Checking stock levels • Dealing with damaged, contaminated stock that has been returned to the pharmacy • Maintaining accurate records/documentation
		5.4	Describe the procedures for the safe handling and disposal of waste materials when maintaining stock
		5.5	Describe how automation is used to control stock

Learning outcomes		Assessment criteria	
6	Be able to issue pharmaceutical stock	6.1	Describe the procedure for responding to urgent requests
		6.2	Describe the different forms of medicines and why it is important to supply appropriate quantities of the correct form and strength
		6.3	Identify and take action if stock is not fit for purpose
		6.4	Describe what products need special packaging and transportation, including cold chain requirements, and explain why it is important to adhere to these requirements
		6.5	Demonstrate how to accurately assemble and issue stock
		6.6	Demonstrate how to supply stock to the correct destination using the correct delivery method
		6.7	Describe the types of documentation completed in relation to the issuing and distribution of medicines

Unit content

What needs to be learned
Learning outcome 1: Understand governance requirements relating to managing pharmaceutical stock
1A Legal and Current organisational policies and guidelines: may include that which is relevant to: supply medicines, ordering licensed, unlicensed and clinical trials medication, data protection, equality and diversity, health and safety
1B Regulatory: General Pharmaceutical Council Professional Standards, current National Institute for Health and Care Excellence (NICE) guidance, Medicines Health Products and Regulatory Agency (MHRA) drug alerts and recalls
1C Managing: ordering, receiving and maintaining
1D Standard Operating Procedures: risk management, incident management and error reporting systems, safe storage of medicines, handling of different drugs, automated ordering, use of technology, use of personal protective equipment (PPE)
Learning outcome 2: Understand pharmaceutical stock
2A Different types of drug formulations: solid doses (tablets, capsules), pessaries, vaginal creams and tablets, suppositories and enemas, internal liquids, external liquids, topical preparations, inhalers and nebulisers, patches, injections, implants, drops, nasal sprays, granules, powders 2B Importance: impact of lack of stock on individual care, health and wellbeing
Learning outcome 3: Be able to order pharmaceutical stock
3A Requirements: quantities, formulations, strength, urgent stock, different ordering processes and impact of seasonal and regional requirements
3B Pharmaceutical Stock: correct item(s), form, strength, amount required, doses, the impact of the formulation on the route of administration
3C Standard Operating Procedures: accurate inputting, storage and retrieval of data to ensure stock levels are appropriate in accordance with organisational procedures
Learning outcome 4: Be able to receive pharmaceutical stock
4A Drug alerts and recalls: safeguarding patient health; confirm suitability for use
4B Standard Operating Procedures: current local guidelines that apply to the receipt of pharmaceutical stock including documentation requiring completion upon receipt of orders; accurate inputting and retrieval of data to ensure stock levels are appropriate in accordance with organisational procedures
4C Appropriate action: what to do if order is incomplete or contains a discrepancy and who to report to

Learning outcome 5: Be able to maintain pharmaceutical stock

5A Action: local and national recall procedures, how and why these are initiated and followed.

5B Store and maintain: storage requirements, safe and secure storage requirements, environmental monitoring, environmental factors, stock rotation procedures, put stock into a location, select shortest dated stock first, check expiry dates, remove expired stock and take appropriate action, rotate stock, check stock levels, stock holding matches stock balance, report discrepancies, deal with damaged, contaminated stock returned to the pharmacy, waste management procedures, maintain accurate records and documentation, refrigeration, ventilation and isolation of stock

Learning outcome 6: Be able to issue pharmaceutical stock

6A Urgent requests: critical medicines, emergency order

6B Different forms of medicines: solid doses (tablets, capsules), pessaries and vaginal creams, suppositories and enemas, internal liquids, external liquids, topical preparations, inhalers and nebulisers, patches, injections, implants, drops, nasal sprays, granules, powders

6C Appropriate quantities: original pack, part packs, stock level requirement, course of treatment

6D Form and strength: appropriate form for route of administration, appropriate strength to achieve dose

6E Not fit for purpose: expired or short dated, packaging not intact or damaged, packaging contaminated or unclean

6F Special packaging: special labelling (fragile, heavy, urgent, cytotoxic medicine, refrigerated item), secure containers, protective packaging, insulated containers, ice packs

6G Assemble and issue stock: requisition, selection of products, and devices, quantity, package, labelling and accurate documentation

6H Documentation: electronic and paper records, including, prescriptions, patient medication records, MARS charts, Cold chain documentation, controlled drugs documentations, clinical trials documentation and others related to Medicines Health Products and Regulatory Agency (MHRA) drug alerts/recalls process, Falsified Medicines Directive, Wholesale dealers license and Contracts with suppliers for medicines and medicinal products

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books and electronic resources.

Assessment

This section must be read in conjunction with *Section 8 Assessment*.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning outcome 1: Understand governance requirements relating to managing pharmaceutical stock

An example of a suitable assignment to cover this learning outcome could be a poster, accompanied by a presentation, displayed in a work area as a reference for staff on governance requirements for the management of pharmaceutical stock. The poster and presentation would need to provide reasons for the importance of following Standard Operating Procedures and identify the limitations of own role and when to refer to others. The presentation can be recorded and submitted as evidence.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Give a clear account of the legislation, regulatory and current organisational guidelines that apply to managing pharmaceutical stock, using their own words and including relevant information (AC1.1)
- 2 Give reasons why it is important to follow Standard Operating Procedures (SOPs) for the management of pharmaceutical stock, providing examples to support the points made (AC1.2)
- 3 Give reasons for referring to others, identifying the limitations of own role within examples provided (AC1.3)

Learning outcome 2: Understand pharmaceutical stock

An example of a suitable assignment to cover these learning outcomes could be a guidance booklet to be kept in the work area as a reference for new members of staff covering the types of drug formulations, importance of ensuring stock is available and sources and suppliers of stock. The booklet would also contain information on the difference between branded and generic medicines.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide details of the different types of drug formulations available within pharmacy stock, giving examples to support points (AC2.1)
- 2 Provide details of the difference between branded and generic medicines, giving examples to support the descriptions (AC2.2)
- 3 Give reasons why it is important to ensure that stock is available to individuals, giving examples to support points made (AC2.3)
- 4 Provide details of different sources and suppliers of stock, giving reasons and examples to support points made (AC2.4)

Learning outcome 3: Be able to order pharmaceutical stock

Learning outcome 4: Be able to receive pharmaceutical stock

An example of a suitable assignment to cover these learning outcomes could be a summary of a Standard Operating Procedure (SOP) covering the order and receipt of pharmaceutical stock. The summary would include the order requirements for pharmaceutical stock prior to placing the order, explain the importance of referring to

drug alerts and recalls when receiving pharmaceutical stock and how to deal with discrepancies with received pharmaceutical stock.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide details of **at least 3 routine** and **3 more complex** order requirements for pharmaceutical stock (AC3.1)
- 2 Give reasons why it is important to refer to current drug alerts and recalls when receiving pharmaceutical stock, giving examples to support points made (AC4.1)
- 3 Provide details of how to take appropriate action to deal with discrepancies in relation to received pharmaceutical stock and include who to report to, giving examples to support points made (AC4.3)

Assessment criteria 3.2 and 4.2 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Learning outcome 5: Be able to maintain pharmaceutical stock

An example of a suitable assignment to cover these learning outcomes could be a guidance booklet for new members of staff covering the importance of monitoring and maintaining a safe, secure and clean working environment which includes a summary the procedure for safe handling and disposal of waste material when maintaining stock.

The guide would summarise the action to take when drug alerts of recalls are received and cover how automation is used to control stock.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Give reasons why it is important to monitor and maintain a safe, secure and clean working environment, giving examples to support points made (AC5.1)
- 2 Provide details of the action to take when drug alerts or recalls are received, giving examples to support points made (AC5.2)
- 3 Provide details of the procedures for the safe handling and disposal of waste materials when maintaining stock, giving examples to support points made (AC5.4)
- 4 Provide details of how automation is used to control stock, giving examples to support points made (AC5.5)

Assessment criterion 5.3 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Learning outcome 6: Be able to issue pharmaceutical stock

An example of a suitable assignment to cover these learning outcomes could be a training guide for the induction of new members of staff, covering the issue of pharmaceutical stock including the procedure for responding to urgent requests. The training guide would need to provide a summary of different forms of medicines including the reasons why it is important to supply appropriate quantities of the correct strength and form as well as explaining how to identify stock that is not fit for purpose and the appropriate action to take. It would also detail special packaging and transportation requirements and explain why they must be adhered to. The guide would provide a summary of the documentation that must be completed in relation to the issuing and distribution of medicines.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide details of the procedure for responding to urgent requests, giving examples to support points made (AC6.1)
- 2 Provide details of **at least 8** different forms of medicines and give reasons why it is important to supply appropriate quantities of the correct form and strength, giving examples to support points made (AC6.2)
- 3 Provide details of identifying when stock is not fit for purpose and taking appropriate action, giving examples to support points (AC6.3)
- 4 Provide details of what products need special packaging and transportation, including cold chain requirements, and explain why it is important to adhere to these requirements, giving examples to support points made (AC6.4)
- 5 Provide details of the types of documentation completed in relation to the issuing and distribution of medicines, giving examples to support points made (AC6.7)

Assessment criteria 6.5 and 6.6 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

Unit 7: Principles of Safe Preparation and Manufacturing of Medicines and Pharmaceutical Products

Level:	2
Unit type:	Optional
Credit value:	10
Guided learning hours:	70

Unit introduction

The aim of this unit is to provide learners with the knowledge, understanding and skills to be able to work safely in the preparation of pharmaceutical products within a specialist preparation/manufacturing environment. Learners must be able to accurately perform simple pharmaceutical calculations to support assembly, in-process checking and preparation of medicines and medicinal products. They should be able to demonstrate a range of techniques used to produce products safely and accurately.

In this unit you will develop your understanding of Good Manufacturing Practice and the legislation and Standard Operating Procedures that govern all areas relating to the preparation and manufacture of medicines.

You will gain an understanding of the different types of manufacturing, the range of environments used for pharmaceutical manufacturing and their individual requirements. You will understand the importance of hygiene and the sources of different types of contamination and the potential consequences linked to these areas.

You will also be able to demonstrate your ability to perform accurate calculations and complete the different types of documentation required in each of the manufacturing environments for all the different processes to ensure that a valid audit trail is maintained.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Understand governance requirements for the manufacture of pharmaceutical products	1.1	Describe legal and current organisational guidelines that apply to the manufacture of pharmaceutical products
		1.2	Describe how Good Manufacturing Practice (GMP) applies to the manufacture of pharmaceutical products
		1.3	Describe the difference between batch manufacturing and preparing a product for an individual patient
		1.4	Explain the importance of following Standard Operating Procedures in relation to the manufacture of pharmaceutical products
		1.5	Explain the limitations of own role and when to refer to an appropriate person
2	Understand the requirements for environmental and personal hygiene within pharmaceutical manufacturing	2.1	Describe the different types of environment used in the manufacture of pharmaceutical products
		2.2	Describe how these environments are monitored and suitably maintained for the manufacture of pharmaceutical products
		2.3	Explain the different sources of contamination which affect the manufacture of pharmaceutical products
		2.4	Outline the impact of contamination within pharmaceutical manufacturing
		2.5	Explain the personal hygiene requirements and why these are important
3	Be able to accurately perform calculations within pharmaceutical preparation and manufacturing	3.1	Explain the importance of performing accurate calculations
		3.2	Demonstrate how to calculate quantities

Learning outcomes		Assessment criteria	
4	Be able to support the processing and manufacturing of pharmaceutical products	4.1	Demonstrate adherence to relevant gowning up procedures and personal hygiene requirements
		4.2	Identify the different types of pharmaceutical products
		4.3	Demonstrate the different manufacturing techniques used to make pharmaceutical products
		4.4	Outline the different methods of sterilisation
		4.5	Demonstrate how to maintain the correct storage conditions for manufactured pharmaceutical products
		4.6	Demonstrate how to clean and decontaminate equipment and preparation area
		4.7	Demonstrate the process for the safe handling and disposal of hazardous waste relating to the manufacture of pharmaceutical products
5	Understand the quality requirements in manufacturing pharmaceutical products	5.1	Outline the packaging and labelling requirements for manufactured pharmaceutical products
		5.2	Identify the documentation used in the manufacture of pharmaceutical products
		5.3	Demonstrate quality assurance and quality control systems in relation to manufacturing pharmaceutical products

Unit content

What needs to be learned
Learning outcome 1: Understand governance requirements for the manufacture of pharmaceutical products
1A Legal and current organisational guidelines: Medicines Act 1968; Human Medicines Regulations 2012; licensing and requirements process, health and safety, control of substances hazardous to health
1B Good Manufacturing Practice standards: EU Directive on Good Manufacturing Practice for Human Medicinal Products; Rules and Guidance for Pharmaceutical Manufacturers and Distributors and current appendices there of (Orange Guide); Quality Assurance of Aseptic Preparation Services (current edition) EL(97) 52; Good Distribution Practice; Good Automated Manufacturing Practice (GAMP)
1C Standard operating procedures: risk management, incident management and error reporting systems, safe storage of medicines, handling of different drugs, use of personal protective equipment (PPE)
Learning outcome 2: Understand the requirements for environmental and personal hygiene within pharmaceutical manufacturing
2A Environment: cleanrooms and support rooms, isolators; air handling units; High Efficient Particulate Air (HEPA) filters; sterile, non-sterile and aseptic environments, monitoring
2B Sources of contamination: particles; micro-organisms; chemical/cross contamination
2C Hygiene: procedure relating to personal presentation, clothes washing, use of Personal Protective Equipment (PPE), showering, effect on environment, products and therefore safety of individuals
Learning outcome 3: Be able to accurately perform calculations within pharmaceutical preparation and manufacturing
3A Calculate quantities: weights; volumes; small quantity calculations; use of formulae; quantity required based on number of prescribed doses and frequency; reconciliation of labels
Learning outcome 4: Be able to support the processing and manufacturing of pharmaceutical products
4A Pharmaceutical products: variety of sterile, non-sterile and aseptic prepared products
4B Techniques: mixing, size reduction; doubling up; filtration; aseptic

Learning outcome 5: Understand the quality requirements in manufacturing pharmaceutical products

5A Packaging and labelling: packaging components, cold chain, labelling requirements in line with legislation, labelling equipment

5B Documentation: certificates of analysis and conformity; data integrity; documentation and system control in pharmacy manufacturing: local Standard Operating procedures; working procedure manuals; batch worksheets or records and associated documents

5C Quality assurance: product contamination by personnel, environment and personnel monitoring; shelf life and stability testing; statutory requirements on quality of pharmaceutical raw materials and formulated products; packaging, labelling and quarantine of completed products

5D Quality control: contamination or impurities in pharmaceutical materials and formulated products, their sources and control; in-process testing

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, electronic resources, documents and legislation.

Assessment

This section must be read in conjunction with *Section 8 Assessment*.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning outcome 1: Understand governance requirements for the manufacture of pharmaceutical products

An example of a suitable assignment to cover these learning outcomes could be a guidance booklet to be kept in the area as a reference for new members of staff covering the legislation and guidelines relating to the manufacture of pharmaceutical products. The booklet would describe how Good Manufacturing Practice applies to the manufacture of pharmaceutical products and explain the importance of adhering to Standard Operating Procedures and recognising the limitations of own role and when to refer to others. The booklet would need to detail batch manufacturing and preparation of products for individuals.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Give a clear account of legal and current organisational guidelines that apply to the manufacture of pharmaceutical products, using their own words and including relevant information (AC1.1)
- 2 Give a clear account of how Good Manufacturing Practice (GMP) applies to the manufacture of pharmaceutical products, using their own words and including relevant information (AC1.2)
- 3 Provide details of the difference between batch manufacturing and preparing a product for an individual patient, giving examples to support information (AC1.3)
- 4 Give reasons why it is important to following Standard Operating Procedures (SOPs) in relation to the manufacture of pharmaceutical products, providing examples to support the points made (AC1.4)
- 5 Give reasons for referring to others, identifying the limitations of own role within examples provided (AC 1.5)

Learning outcome 2: Understand the requirements for environmental and personal hygiene within pharmaceutical manufacturing

An example of a suitable assignment to cover this learning outcome could be a poster, accompanied by a presentation, displayed in a work area as a reference for staff detailing the different work environments used and how they are monitored and suitably maintained for the manufacture of pharmaceutical products. The poster and presentation would detail different sources of contamination and the impact of these within pharmaceutical manufacturing as well as identifying the importance and basic requirements of personal hygiene. The presentation can be recorded and submitted as evidence.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide details of the different types of environment used in the manufacture of pharmaceutical products, giving examples to support points (AC 2.1)
- 2 Provide details of how these environments are monitored and suitably maintained for the manufacture of pharmaceutical products, giving examples to support points made (AC 2.2)
- 3 Provide details of **at least 3** different sources of contamination which affect the manufacture of pharmaceutical products (AC 2.3)
- 4 Provide details of the impact of contamination within pharmaceutical manufacturing, giving examples to support points (AC 2.4)
- 5 Give reasons why it is important to maintain Personal hygiene explaining what the requirements are, using their own words (AC 2.5)

Learning outcome 3: Be able to accurately perform calculations within pharmaceutical preparation and manufacturing

An example of a suitable assignment to cover this learning outcome could be to complete a selection of sample worksheets for a variety of products. Learners would need to calculate quantities and dosages for each product, explaining the importance performing calculations accurately and the possible consequences of making errors.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Give reasons why it is important to perform accurate calculations, providing examples to support points made (AC 3.1)

Assessment criterion 3.2 assess skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Learning outcome 4: Be able to support the processing and manufacturing of pharmaceutical products

An example of a suitable assignment to cover this learning outcome could be a chart detailing the types of pharmaceutical products manufactured and the sterilisation methods used. Where possible, the learners should use examples from their own workplace.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide details of **at least 3** different types of pharmaceutical products, giving examples to support the points (AC 4.2)
- 2 Provide details of the different methods of sterilisation, giving examples to support points (AC 4.4)

Assessment criteria 4.1, 4.3, 4.5, 4.6 and 4.7 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Learning outcome 5: Understand the quality requirements in manufacturing pharmaceutical products

An example of a suitable assignment to cover this learning outcome could be a chart of the range of pharmaceutical products manufactured, detailing their packing and labelling requirements, and documentation used to maintain quality assurance. Where possible, the learners should use examples from their own workplace.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 Provide details of the packaging and labelling requirements for manufactured pharmaceutical products, giving examples to support points (AC 5.1)
- 2 Provide details of the documentation used in the manufacture of pharmaceutical products, giving examples to support points (AC 5.2)

Assessment criterion 5.3 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

Unit 8: Selling Over the Counter Medicines and Medicinal Products

Level:	2
Unit type:	Optional
Credit value:	10
Guided learning hours:	70

Unit introduction

This unit aims to develop learners' knowledge and understanding of their own roles and responsibilities and the role of the pharmacy team in relation to the sale of over the counter (OTC) medicines and medicinal products; providing advice to individuals on the safe and effective use of non-prescribed medicines and devices. Learners will develop skills enabling them to identify individual needs and recommend suitable over the counter medicines and products.

This unit will help equip you with the knowledge required to work effectively and safely on the medicine counter and the skills to communicate with individuals using appropriate questioning techniques and in a way which meets their needs. You will consider the importance and impact of your role within the pharmacy environment and gain the knowledge required to work effectively and safely on the medicine counter. The unit identifies use of standard operating procedures (SOPs) and the importance of working within the limits of your own role.

You will also learn to identify different classes of medicines, their uses and side effects, helping you to choose suitable products to sell to individuals or refer to the pharmacist.

You will learn how to use resources to provide advice and information to individuals and how to choose the most appropriate information in line with the current guidelines and safe practice for over the counter.

Learning outcomes and assessment criteria

To pass this unit, the learner needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria determine the standard required to achieve the unit.

Learning outcomes		Assessment criteria	
1	Be able to identify individual needs for medicines and products within a pharmacy setting	1.1	Communicate with individuals in a manner that is appropriate to their needs in line with local and national protocols
		1.2	Demonstrate the use of appropriate questioning techniques to obtain relevant information to identify individual needs for a medicine or product.
2	Be able to recommend suitable over the counter medicines and products	2.1	Describe the difference between the classes of medicines
		2.2	Demonstrate how different classes of medicines affect an over the counter sale
		2.3	Explain the impact of changes to classes of medicines on the sale of over the counter medicines
		2.4	State uses, side effects and contra-indications for commonly used over the counter medicines
		2.5	Demonstrate the use of appropriate information that should be given to individuals when selling a range of different commonly used over the counter items

Learning outcomes		Assessment criteria	
3	Understand how to assist in the provision of pharmacy services	3.1	Outline the roles and responsibilities of the pharmacy and wider healthcare team
		3.2	Apply national and local requirements and standard operating procedures (SOPs) in relation to over the counter medicines and products
		3.3	Recognise poor performance of others and take appropriate action
		3.4	Identify resources that can be used to ensure that product knowledge remains up to date and explain why it is important to keep product knowledge up to date

Unit content

What needs to be learned
Learning outcome 1: Be able to identify individual needs for medicines and products within a pharmacy setting
1A Communication: national protocols; questioning techniques, open questions; closed questions, clear speech, age-appropriate language, formal and informal language, active and reflective listening techniques, adapt communication to meet specific needs of the individual, preferences of the individual, tools and methods of communication, types of communication, verbal and non-verbal
1B Individuals: those with special requirements; specific language needs, those with no idea of their needs; those with a clear idea of their needs; customer's representative; those presenting with symptoms
1C Questioning techniques to assess individual needs: open and closed questions, funnel questions, probing questions, advice on symptoms; named products; healthcare advice e.g. dietary, smoking cessation, 2WHAM
Learning outcome 2: Be able to recommend suitable over the counter medicines
2A Classes of medicines: General Sales Medicines (GSM); Pharmacy (P); Prescription Only Medicines (POM), products available in different pack sizes
2B Changes to classes of medicines: Up-to-date knowledge: product knowledge including new products; legislation including POM to P switches, over the counter medicines liable to misuse or abuse, the difference between misuse and abuse of over the counter medicines, requests for regular quantities of medicines liable to abuse or misuse
2C Commonly used over the counter medicines: products available for various areas including coughs and colds, indigestion and heartburn, constipation and diarrhoea, pain, hay fever, skin, dental, women's health, men's health
2D Information that should be given to individuals: where to find information; standard operating procedures, protocols, MIMS, BNF, suppliers'/manufacturers' information, healthcare leaflets; different formats; oral, written e.g. patient information leaflets, electronic; Information about products: uses, recommended doses, contra- indications, side effects; healthcare advice: smoking cessation, dietary advice, health promotion activities and services

Learning outcome 3: Understand how to assist in the provision of pharmacy services

3A Roles and responsibilities: legal and ethical responsibilities of team members, when medicines may not be sold, confidentiality, protocols, when to refer: request for product or advice outside limits of own job role; sale of medicines to the elderly, children, pregnant women, requests for medicines with the same or similar active ingredients, requests for regular quantities of medicines liable to abuse or misuse

3B National and Local requirements: follow organisational procedures for the sale of over the counter medicines and medicinal products, Standard Operating Procedures, Medicines Act 1968, Human Medicines Regulations 2012, Falsified Medicines, MHRA

3C Standard Operating Procedures: pharmacy protocol; Responsible Pharmacist; staff training requirements

3D Take appropriate action: referral to the appropriate workplace representative, referral to the General Pharmaceutical Council (GPhC), whistleblowing

3E Keep product knowledge up to date: continued professional development (CPD), over the counter medicine product knowledge, local policy, minor ailment schemes, the importance of keeping product knowledge up to date

Essential information for tutors and assessors

Essential resources

Learners undertaking this qualification will need access to a pharmacy, a registered pharmacist and other members of the pharmacy team (for example a pharmacy technician) to act as supervisors or mentors.

Staff delivering this unit should be occupationally competent and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and be able to demonstrate evidence of continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources.

Assessment

This section must be read in conjunction with *Section 8 Assessment*.

This unit is internally assessed. To pass this unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

The assessment for this unit should be set in a specific organisational context, it should draw on learning from the unit and be designed in a way that enables learners to meet all the assessment criteria.

A recommended assessment approach is given below. Centres are free to create their own assessment as long as they are confident it enables learners to provide suitable and sufficient evidence to meet the stated standard of the assessment criteria and achieve the learning outcomes.

Learning outcome 1: Be able to identify individual needs for medicines and products within a pharmacy setting

An example of a suitable assignment to cover this learning outcome could be a poster, accompanied by a presentation, to display for the pharmacy team to use that details communication methods used for selling OTC medicines and products. The poster and presentation will need to include details of questioning techniques and methods for assessing individual needs, including those with special requirements. The presentation can be recorded and submitted as evidence.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 briefly set out **at least three** communication methods used for individuals in line with local and national protocols (AC1.1).

Assessment criterion 1.2 covers the assessment of skills. The primary method of assessment for this assessment criterion is observation in the workplace by the assessor.

Learning outcome 2: Be able to recommend suitable over the counter medicines

An example of a suitable assignment to cover this learning outcome could be a pocket guide for use by pharmacy staff detailing the different classes of medicines, medicine legislation and misuse and abuse of over the counter medicines. The pocket guide will need to include examples of commonly used over the counter medicines and information that should be given to individuals when making over the counter sales. This should include different formats of information and advice given to individuals.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 briefly set out the different classes of medicines, using examples to support the points made (AC2.1).
- 2 provide details of how different medicine classes may affect an over the counter sale and the impact of changes to classes of medicines, giving reasons and examples (AC2.3).
- 3 briefly set out uses, side effects and contra-indications for **at least three** commonly used over the counter medicines, using their own words and including all the relevant information (AC2.4).

Assessment criteria 2.2 and 2.5 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Learning outcome 3: Understand how to assist in the provision of pharmacy services

An example of a suitable assignment to cover this learning outcome could be a continued professional development (CPD) information booklet for use by the pharmacy team. The information booklet will need to include the roles and responsibilities of the pharmacy team members, how Standards Operating Procedures are used and when referral would be appropriate in the provision of pharmacy services. Ways to keep product knowledge and available services up to date should also be included.

To satisfy the assessment criteria for this learning outcome, learners will:

- 1 briefly set out the roles and responsibilities of the pharmacy and wider healthcare team, using examples to support the points made (AC3.1).
- 2 give reasons why it is important to keep product knowledge up to date and provide examples of resources used, using their own words and including all the relevant information (AC3.4).

Assessment criteria 3.2 and 3.3 cover the assessment of skills. The primary method of assessment for these assessment criteria is observation in the workplace by the assessor.

Assessment

This unit is internally assessed. To pass the unit, the evidence that the learner presents for assessment must demonstrate that they have met the required standard specified in the learning outcomes and assessment criteria.

It is expected that this unit will be assessed in a real or simulated working environment, where evidence is naturally occurring and collected over a period of time.

Centres are responsible for deciding on the assessment activities that will enable learners to produce valid, sufficient, authentic and appropriate evidence to meet the assessment criteria. When planning assessment and evidence collection for the unit, centres should consider the nature and sources of the evidence required for the portfolio that supports the interview in the end-point assessment. This ensures that learners have evidence that supports their interview responses.

Learners must be given a clear assessment brief before the assessment takes place, detailing:

- the assessment activity and context
- the learning outcome(s) to be assessed
- the criteria they are expected to meet, and
- the time and duration of the assessment.

Wherever possible, centres should adopt a holistic and integrated approach to assessing the skills units in the qualifications. This gives the assessment process greater rigour, minimises repetition and saves time. The focus should be on assessment activities generated through naturally occurring evidence in the workplace rather than on specific tasks. Taken as a whole, the evidence must show that the learner meets all learning outcomes and assessment criteria over a period of time. It should be clear in the assessment records where each learning outcome and assessment criterion has been covered and achieved.

13 Suggested teaching resources

This section lists resource materials that can be used to support the delivery of the qualification.

Textbooks

Beaney A – *Quality Assurance of Aseptic Preparation Services: Standards Handbook*, 5th edition (Royal Pharmaceutical Society, 2016) ISBN 9780857113078

Boarder M, Dixon J (et al) – *Pharmacology for Pharmacy and the Health Sciences: A Patient-centred Approach*, 2nd edition (Oxford University Press, 2016) ISBN 9780198728832

British National Formulary, current edition (Pharmaceutical Press, published bi-annually in March and September)

Clendon J, Munns A – *Community Health and Wellness: Principles of Primary Healthcare*, 6th edition (Elsevier, 2018), ISBN 9780729542746

Dorling Kindersley – *BMA New Guide to Medicines and Drugs*, 10th edition (Dorling Kindersley, 2018) ISBN 9780241317617

Harman R, Mason P (editors) – *Handbook of Pharmacy Healthcare*, 2nd edition (Pharmaceutical Press, 2002) ISBN 9780853695073

Mandelstam M – *Safeguarding Adults and the Law: An A-Z of Law and Practice*, 3rd edition (Jessica Kingsley Publishers, 2019) ISBN 9781785922251

Merrills J, Fisher J – *Pharmacy Law and Practice*, 5th edition (Academic Press, 2013) ISBN 9780123942890

MHRA (Medicines Healthcare and Products Regulatory Authority) – *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2017 (The Orange Guide)*, 10th edition (Pharmaceutical Press, 2017) ISBN 9780857112859

Naidoo J, Wills J – *Foundations for Health Promotion*, 4th edition (Elsevier, 2016) ISBN 9780702054426

Nathan A – *Non-Prescription Medicines*, 4th edition (Pharmaceutical Press, 2010) ISBN 9780853698869

Royal Pharmaceutical Society – *Medicines, Ethics and Practice*, current edition (Pharmaceutical Press, published annually in July)

Stringer J – *Basic Concepts in Pharmacology: What You Need to Know for Each Drug Class*, 5th edition (McGraw-Hill, 2017) ISBN 9781259861079

Thistlethwaite J, McKimm J – *Health Care Professionalism at a Glance* (Wiley-Blackwell, 2015) ISBN 9781118756386

Walker R, Whittlesea C – *Clinical Pharmacy and Therapeutics*, 6th edition (Elsevier, 2018)
ISBN 9780702070129

Wingfield J, Pitchford K – *Dale and Appelbe's Pharmacy and Medicines Law*, 11th edition
Pharmaceutical Press, 2017) ISBN 9780857112026

Journals

NICE Journals and databases – www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases

Pharmaceutical Journal – www.rpharms.com/publications/pharmaceutical-journal

Pharmaceutical Journal *How Pharmacy can Provide Patient Centred Care for Dementia Patients* www.pharmaceutical-journal.com/learning/learningarticle.how-pharmacy-can-provide-patient-centred-care-for-dementiapatients/20203385.article

Documents

EudraLex – Volume 4 Good Manufacturing Practice (GMP) guidelines – ec.europa.eu/health/documents/eudralex/vol-4

The supply of unlicensed medicinal products “special” MHRA guidance note 14 – www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

Legislation

The Medicines Act 1968 – www.legislation.gov.uk/ukpga/1968/67

The Human Medicines Regulations – www.legislation.gov.uk/uksi/2012/1916/contents/made

Directive 2001/83/EC (Human medicines) – ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf

Directive 2003/94/EC (Good Manufacturing Practice) – ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2003_94/dir_2003_94_en.pdf

Directive 2011/62/EU (Falsified Medicines Directive) - ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

Websites

www.aptuk.org	Association of Pharmacy Technicians.
bnf.nice.org.uk	British National Formulary.
www.cppe.ac.uk	Centre for Pharmacy Postgraduate Education.
www.doh.gov.uk	Department of Health and Social Care.
www.gov.uk/government/organisations/public-health-england	Public Health England.
www.health.org.uk	The Health Foundation.
www.hps.scot.nhs.uk/	Health Protection Scotland.
www.hse.gov.uk	Health and Safety Executive.
www.legislation.gov.uk	The National Archives.
www.medicines.org.uk/emc	Electronic Medicines Compendium.
www.medicinescomplete.com	Medicines Complete.
www.mhra.gov.uk	Medicines and Healthcare Products Regulatory Agency.
www.nhs.uk	NHS Choices.
www.nice.org.uk	National Institute for Health and Care Excellence.
www.pharmaceutical-journal.com	Pharmaceutical Journal Online.
www.pharmacyregulation.org	General Pharmaceutical Council.
psnc.org.uk	Pharmacy Services Negotiating Committee.
www.publichealth.ie	Public Health Ireland.
phw.nhs.wales	Public Health Wales.
www.rpharms.com	Royal Pharmaceutical Society.
www.sps.nhs.uk	Specialist Pharmacy Service.
Apps (available on Apple and Android)	
BNF	British National Formulary.
BNFC	British National Formulary for Children.

14 Further information and useful publications

- Edexcel, BTEC and Pearson Work Based Learning contact details: qualifications.pearson.com/en/support/contact-us.html.
- Books, software and online resources for UK schools and colleges: www.pearsonschoolsandfecolleges.co.uk
- Key publications
 - *Access arrangements and reasonable adjustments* (Joint Council for Qualifications (JCQ))
 - *A guide to recruiting learners onto Pearson qualifications* (Pearson)
 - *A guide to the special consideration process* (JCQ)
 - *Pearson Centre Guide to Quality Assurance NVQs/SVQs and Competence-based qualifications*
 - *BTEC Centre Guide to Managing Quality* (Pearson)
 - *BTEC Quality Assurance Centre Handbook* (Pearson)
 - *Collaborative and consortium arrangements for the delivery of vocational qualifications policy* (Pearson)
 - *Enquiries and appeals about Pearson vocational qualifications and end point assessment policy* (Pearson)
 - *Equality, diversity and inclusion policy* (Pearson)
 - *Recognition of prior learning policy and process* (Pearson)
 - *Guidance for reasonable adjustments and special consideration in vocational internally assessed units* (Pearson)
 - *Suspected malpractice in examinations and assessments* (JCQ)
 - *UK Information Manual* (updated annually) (Pearson)
 - *Use of languages in qualifications policy* (Pearson).

Publications on the quality assurance of Pearson qualifications are available on our website.

Our publications catalogue lists all the material available to support our qualifications. To access the catalogue and order publications, please visit our website.

Additional resources

If you need further learning and teaching materials to support planning and delivery for your learners, there is a wide range of BTEC resources available.

Any publisher can seek endorsement for their resources and, if they are successful, we will list their BTEC resources on our website.

Annexe A

Assessment Principles for the Level 2 Certificate in the Principles and Practice for Pharmacy Support Staff

1. Introduction

This is a nationally recognised qualification by Ofqual / Qualifications Wales. The qualification is based on National Occupational Standards and is recognised by the statutory regulator, the General Pharmaceutical Council (GPhC), as meeting the [GPhC requirements for the education and training of pharmacy support staff \(effective October 2020\)](#).

This qualification has been designed to confirm occupational competence for pharmacy support staff working in a pharmacy setting. The qualification meets the requirements of the pharmacy regulator and meets employer need in England and Wales.

This qualification also meets the Skills for Health Qualiication Design Criteria.

2. Assessment requirements/strategy

This qualification must be assessed in line with the Awarding Organisation qualification assessment strategy as well as in line with Skills for Health Assessment Principles for Occupational Competence (v4 November 2017).

This qualification consists of both skills units and knowledge units. There are four mandatory units and 4 optional units (of which learners must complete a minimum of one). This qualification will be graded pass or fail.

Learners are permitted to use one piece of evidence to demonstrate knowledge, skills and understanding across different assessment criteria and/or different units. This qualification should incorporate holistic assessment for the units where appropriate.

2.1 Skills-based units

The primary method of assessment for the skills-based units is observation in the workplace by the assessor. Across the qualification's skills-based units there must be at least three observations which cover the required skills. Evidence should be generated over a period of time to show consistent performance. Expert witness testimony may be used where it is difficult for an assessor to observe aspects of practice. Expert witness testimony is NOT a substitute for the requirement of three observations by the assessor across the qualification.

At any time during assessment the assessor observes unsafe practice, the assessment will be stopped immediately.

Where the assessment activity involves individuals using pharmacy services, consent should be sought from the individual/patient that they are happy for the assessor to be present and this should be recorded by the assessor.

Learners will be expected to achieve all learning outcomes and assessment criteria. Where learners are not able to achieve the skills-based learning outcomes in their usual place of employment (e.g. a custodial setting), the training provider and employer must ensure that the learner is given opportunities to achieve the learning outcomes in a work placement or another suitable setting. This may include simulation. Prior to starting the qualification, an assessment of the learner's employment setting should be carried out by the training provider and employer to identify such gaps.

2.2 Knowledge-based units

For knowledge-based units, evidence will be assessed using internally set, internally marked written assignments. The Awarding Organisation will provide sample assignments and assessment guidance to centres. The assignments will be internally quality assured, then subject to externally quality assurance sampling by the Awarding Organisation.

Centres must also carry out regular standardisation activities as part of the ongoing quality assurance of assessment decisions within the assignments used for knowledge-based units and assignments should be refreshed over time.

2.3 Re-takes for knowledge-based units

Learners will be given maximum of four weeks to complete each assignment. If the learner does not pass the assignment on the first attempt, they will be given a maximum of two further opportunities to re-take the assessment criteria that they failed on the first attempt. Re-takes should be submitted within two weeks (for each re-take).

Centres should use recording documentation to record assignment re-take results and feedback.

2.4 Additional assessment methods

In addition to the evidence requirements set out in each unit, a range of assessment methods have been identified for the qualification units which may include evidence generated using the following:

Question and answer sessions based on the learner's workplace activities

Learner's own personal statements/reflections

Professional discussion

The additional assessment methods above should NOT be used instead of or in place of the stated assessment methodology in each unit.

The additional assessment methods provide the opportunity for different learning styles and individual needs of learners to be taken into account. If centres are proposing to use an assessment method that is not included within the recommended list, centres should contact the External Quality Assurer with full details of the proposed method which will need formal approval from the Awarding Organisation before it can be used.

3.Roles and Responsibilities in the Assessment Process

3.1 Assessors

Assessors must:

- be a registered Pharmacist or a registered Pharmacy Technician who is occupationally competent in the area of practice to which the unit being assessed applies
- hold or be working towards the appropriate Assessor qualification. Assessors holding legacy qualifications must be able to demonstrate that they are assessing to current standards
- have credible experience which is clearly demonstrable through continuing learning and development.

3.2 Internal Quality Assurers

Internal Quality Assurers (IQA) must:

- be a registered Pharmacist or a registered Pharmacy Technician
- it is crucial that internal quality assurers understand the nature and context of the assessors' work and that of their candidates due to the critical nature of the work and the legal and other implications of the assessment process
- have a working knowledge of pharmacy and/or GP dispensing settings, the regulation, legislation and codes of practice for the service (where applicable) at the time any assessment is taking place
- occupy a position that gives them authority and resources to co-ordinate the work of assessors, provide authoritative advice, call meetings as appropriate, visit and observe assessments and carry out all the other internal quality assurance roles
- hold or be working towards an appropriate Internal Quality Assurance qualification. Internal quality assurers holding legacy qualifications must be able to demonstrate that they are working to current standards
- have undertaken the appropriate assessor qualification identified by the regulator and practised as an assessor prior to undertaking the internal quality assurer role

It is recognised that internal quality assurers are expected to verify the assessment process and not reassess the evidence provided.

3.3 Expert witnesses

The use of expert witness testimony is encouraged as a contribution to the provision of performance evidence presented for assessment. The role of the expert witness is to submit evidence to the assessor as to the competence of the learner in meeting the unit. This evidence must directly relate to learner's performance in the work place which has been seen by the expert witness.

The expert witness must be either:

- a registered Pharmacist or a registered Pharmacy Technician who is occupationally competent and knowledgeable in the area of practice to which the unit being assessed applies

The expert witness must have:

- a working knowledge of units on which their expertise is based
- credible experience which is clearly demonstrable through continuing learning and development.

Centres are responsible for ensuring that all expert witnesses are familiar with the standards for those units for which they are to provide expert witness testimony. They must also understand the centre's recording requirements and will need guidance on the skills required to provide evidence for the units. It is not necessary for expert witnesses to hold an assessor qualification because the qualified assessor makes all assessment decisions about the acceptability of evidence regardless of source. This would include expert witness testimony.

3.4 Co-ordinating and Lead Assessors

In order that the requirements for occupational competence of assessors and expert witnesses can be met while allowing flexibility of delivery, candidates may have more than one assessor or expert witness involved in the assessment process.

Where more than one assessor is involved in the qualification there must be a named assessor who is responsible for the overall co-ordination of the assessment for each candidate. This person will be responsible for integrating, planning and directing the assessment for the whole qualification. Where more than one assessor is involved in a unit, there must be named assessor who is responsible for the overall coordination of the assessment for that unit. The lead assessor must ensure that the best use is made of all available evidence and will make the final judgment of competence in each unit where other assessors have been involved. It is expected that all assessors will work closely with internal quality assurers to ensure standardised practice and judgments within the assessment process.

3.5 External Quality Assurers

External Quality Assurers (EQA) must:

- be a registered Pharmacist or a registered Pharmacy Technician
- have working knowledge of pharmacy and/or GP dispensing settings, the regulation, legislation and codes of practice for the service (where applicable) at the time any assessment is taking place
- hold, or be working towards, the appropriate external verifier qualification as identified by the qualifications regulators. External quality assessors holding legacy qualifications must be able to demonstrate that they are assessing to current standards
- have credible experience which is clearly demonstrable through continuing learning and development

External quality assessors who are not yet qualified against the appropriate competences but have the necessary occupational competence and experience, can be supported by a qualified external quality assessor who does not necessarily have the occupational expertise or experience.

External Quality Assurers will monitor the centre's processes and practice to ensure they meet the Awarding Organisation, qualification and regulatory requirements. The EQA will also provide support to centre staff and give advice and guidance to facilitate improvements.

Appendix 1

Staff qualification requirements

#	Role	Staff qualifications
#1	Assessment of Competence	<ul style="list-style-type: none"> Assessors must be GPhC registered and occupationally competent in the area of practice to which the unit being assessed applies. Hold or be working towards the appropriate Assessor qualification. Have credible experience which is clearly demonstrable through continuing learning and development.
#2	Assessment of Knowledge	<ul style="list-style-type: none"> As for 'Role #1' Or have credible qualifications and experience which is clearly demonstrable through continuing learning and development.
#3	IQA for Competence	<ul style="list-style-type: none"> Must be GPhC registered and understand the nature and context of the assessors' work and that of their candidates Have a working knowledge of pharmacy and/or GP dispensing settings, the regulation, legislation and codes of practice for the service (where applicable) at the time any assessment is taking place Occupy a position that gives them authority and resources to co-ordinate the work of assessors, provide authoritative advice, call meetings as appropriate, visit and observe assessments and carry out all the other internal quality assurance roles Have undertaken the appropriate assessor qualification and hold or be working towards an appropriate Internal Quality Assurance qualification.
#4	IQA for Knowledge	<ul style="list-style-type: none"> As per Role #3 Or have credible qualifications and experience which is clearly demonstrable through continuing learning and development. Occupy a position that gives them authority and resources to co-ordinate the work of assessors, provide authoritative advice, call meetings as appropriate, and carry out internal quality assurance roles

#	Role	Staff qualifications
#5	Sign-off of the qualification	<ul style="list-style-type: none"> • Must be GPhC registered and understand the nature and context of the assessors' work and that of their candidates • Have a working knowledge of pharmacy and/or GP dispensing settings, the regulation, legislation and codes of practice for the service (where applicable) at the time any assessment is taking place • Occupy a position that gives them authority and resources to co-ordinate the work of assessors, provide authoritative advice, call meetings as appropriate, visit and observe assessments and carry out all the other internal quality assurance roles • Have undertaken the appropriate assessor qualification and hold or be working towards an appropriate Internal Quality Assurance qualification.

Useful links

- General Pharmaceutical Council, *requirements for the education and training of pharmacy support staff*, October 2020
- Skills for Health Assessment Principles
<http://www.skillsforhealth.org.uk/images/standards/qcf/Assessment%20of%20Competence%20-%20SfH%20Assessment%20Principles%20November%2017.pdf>
- Health Education England <https://www.hee.nhs.uk/>

Annexe B

Mapping of the GPhC requirements for the education and training of pharmacy support staff (effective October 2020) to the qualification content

The grid below maps the outcomes for all support staff to the content covered in the Pearson BTEC Level 2 Certificate in the Principles and Practice for Pharmacy Support Staff.

KEY

indicates coverage of the outcome in the qualification

a blank space indicates no coverage of the outcome in the qualification

BTEC Specialist units		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8
Outcomes for all support staff									
1	Act to maintain the interests of individuals and groups, making patients and their safety their first concern		#						
2	Recognise what it means to give person-centred care and support in pharmacy settings, including settings where patients are not physically present	#							
3	Respect diversity and cultural differences, ensuring that person-centred care is not compromised because of personal values and beliefs	#							
4	Listen to and communicate effectively with users of pharmacy services, which could include: • individual	#							#

BTEC Specialist units		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8
Outcomes for all support staff									
	patients • carers • other members of the pharmacy or healthcare team • other health and social care staff using a range of techniques to determine their needs								
5	Adapt information and communication style to meet the needs of particular audiences and communication channels	#							
6	Recognise principles of consent and apply them as appropriate to their role	#							
7	Act to maintain the confidentiality of individuals using pharmacy services	#							
8	Apply the principles of information governance as required by their role	#							
9	Recognise and raise concerns, even when it is not easy to do so, using appropriate systems	#			#				
10	Recognise and raise concerns about safeguarding people, particularly children and vulnerable adults	#							
11	Work effectively as part of the pharmacy team and/or the wider health team			#					
12	Recognise, apply and work within the relevant legal and regulatory requirements, local processes and standard operating procedures as applicable to their own role					#	#	#	#

BTEC Specialist units		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8
Outcomes for all support staff									
13	Recognise and work within the limits of their knowledge and skills, seeking support and referring to others when needed			#	#				
14	Identify the roles and responsibilities of those they work with and functions of the wider pharmacy and healthcare system			#					#
15	Refer issues and/or individuals as appropriate to another member of the pharmacy team, other health and social care staff, organisations or services			#	#				
16	Apply policies around health and safety relevant to their role, including recognising hazards and acting appropriately to avoid harm to themselves and others		#			#	#		#
17	Demonstrate trust and respect for individuals, members of the pharmacy team and health professionals at all times			#					
18	Apply technical knowledge and skills identified as being required for the safe and effective performance of their role in • the dispensing and supply of medicines and medical devices, • advising on their use or • assisting in the provision of pharmacy services ⁴ . This includes applying legal and regulatory requirements, including					#	#	#	#

BTEC Specialist units		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8
Outcomes for all support staff									
	best practice in the context of their role, using relevant systems and accurate performance of pharmacy tasks								
19	Make use of feedback on performance, local HR processes and reflection, to identify and act on their own learning needs				#				

Annexe C

Mapping of the Pharmacy National Occupational Standards (NOS) to the qualification content

The grid below maps the pharmacy national occupational standards to the content covered in the Pearson BTEC Level 2 Certificate in the Principles and Practice for Pharmacy Support Staff.

KEY

indicates coverage of the outcome in the qualification

a blank space indicates no coverage of the outcome in the qualification

BTEC Specialist units		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8
NOS									
PHARM01	Assist with the provision of a pharmacy service			#					#
PHARM02	Provide an effective and responsive pharmacy service	#		#		#			#
PHARM03	Respond to pharmaceutical queries and requests for info	#							
PHARM04	Provide advice on non-prescribed medicines and products								#
PHARM07	Receive prescriptions					#			
PHARM08	Confirm prescription validity					#			
PHARM09	Assemble prescribed items					#			

BTEC Specialist units		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8
NOS									
PHARM10	Issue prescribed items					#			
PHARM12	Order pharmaceutical stock						#		
PHARM13	Receive pharmaceutical stock						#		
PHARM14	Maintain pharmaceutical stock						#		
PHARM15	Supply pharmaceutical stock						#		
PHARM17	Manufacture and assemble medicinal products							#	
PHARM19	Prepare aseptic products and carry out in-process checking							#	
PHARM20	Prepare documentation and materials for the manufacture and assembly of medicinal products							#	
PHARM21	Prepare documentation, materials and other items for the preparation of aseptic products							#	
PHARM23	Check documentation, starting materials, components and other consumables for the production of aseptic products							#	
PHARM25	Supply dressings and appliances					#			
PHARM28	Undertake the final accuracy check of dispensed medicines and products					#			

BTEC Specialist units NOS		Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8
PHARM29	Retrieve and reconcile information about an individual's medicines								#
PHARM32	Assist in the issuing of prescribed items					#			
PHARM33	Order medicines and products for individuals						#		

September 2020

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