Level 2 NVQ Certificate in Pharmacy Service Skills (5355-02)

Qualification handbook for centres

500/9234/0

www.cityandguilds.com
August 2017
Version 3.1

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Date and version No.	Change detail	Section
September 2012 Version 2	Unit 008 Outcome 5 • Changed Range b title from 'Legal, professional and organisational requirements' to 'Current legislation' as this relates to AC1. • Range 'b' now becomes range 'a' and 'SOPs' becomes range b. • Enboldened 'current legislation' in AC1.	Units
May 2013 Version 3	Unit numbers changed to bring in line with Walled Garden	Units
August 2017 Version 3.1	Adding GLH and TQT details Removing QCF	Introduction Throughout

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Contents

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1 Introduction to the qualification

This document contains the information that centres need to offer the following qualification:

Qualification title and level	Level 2 NVQ Certificate in Pharmacy Service Skills
GLH	62
TQT	200
City & Guilds qualification number	5355-02
Qualification accreditation number	500/9234/0
Registration and certification	Consult the Walled Garden/Online Catalogue for last dates

This qualification has been designed for those working in a pharmacy setting, either in the community or in a hospital. The qualification meets the needs of the pharmacy sector and related sector regulators and the requirements for endorsement of Skills for Health as the relevant Sector Skills Council for use in England, Wales and Northern Ireland. The qualification is based upon newly developed National Occupational Standards for Pharmacy and is appropriate as a stand alone qualification for those working in Pharmacy support services at Level 2. To achieve the qualification, candidates must complete three mandatory units. Candidates must also complete a minimum of four optional units from a choice of thirteen.

1.1 Qualification structure

To achieve the **Level 2 NVQ Certificate in Pharmacy Services Skills (5355-02)**, learners must achieve **8** credits from the mandatory units and a minimum of **12** credits from at least 4 of the optional units available, for a minimum of **20** credits.

The table below shows the unit titles and the credit value of each unit.

Unit accreditation number	City & Guilds unit number	Unit title	Mandatory/ optional for full qualification	Credit value
L/601/3394	201	Assist with the provision of a pharmacy service to meet individuals' needs	Mandatory	3
R/600/9413	202	Ensure your own actions reduces risks to health and safety	Mandatory	2
L/601/3430	203	Contribute to the effectiveness of teams	Mandatory	3
M/600/9371	204	Assist in the sale of medicines and products	Optional	8
T/601/3468	305	Receive prescriptions from individuals	Optional	3
Y/601/3432	206	Assemble prescribed items	Optional	3
J/600/9375	207	Order routine pharmaceutical stock	Optional	3
M/600/9385	311	Receive pharmaceutical stock	Optional	3
T/600/9386	312	Maintain pharmaceutical stock	Optional	3
Y/600/9378	210	Assist in the issuing of pharmaceutical stock	Optional	4

Unit accreditation number	City & Guilds unit number	Unit title	Mandatory/ optional for full qualification	Credit value
D/601/3433	211	Assist in the manufacture and assembly of medicinal products	Optional	7
M/601/3436	212	Prepare aseptic products	Optional	10
H/601/3448	213	Prepare documentation, materials, components and other items for the preparation of aseptic products	Optional	6
D/601/3450	214	Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products	Optional	10
Y/600/9395	314	Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check	Optional	4
D/600/9379	216	Assist in the issuing of prescribed items	Optional	3

Total Qualification Time

Total Qualification Time (TQT) is the total amount of time, in hours, expected to be spent by a Learner to achieve a qualification. It includes both guided learning hours (which are listed separately) and hours spent in preparation, study and assessment.

Title and level	GLH	TQT
Level 2 NVQ Certificate in Pharmacy Service Skills	62	200

1.2 Opportunities for progression

Candidates who complete the Level 2 NVQ Certificate in Pharmacy Service Skills might be able to progress on to the City & Guilds' Level 3 NVQ Diploma in Pharmacy Service Skills.

1.3 Qualification support materials

City & Guilds also provides the following publications and resources specifically for this qualification:

Description	How to access
Recording forms	**www.cityandguilds.com**

2 Centre requirements

This section outlines the approval processes for Centres to offer this qualification and any resources that Centres will need in place to offer the qualifications including qualification-specific requirements for Centre staff.

Centres already offering City & Guilds qualifications in this subject area

Centres currently offering the City & Guilds Level 2 NVQ in Pharmacy Services (7355) will receive automatic approval to offer the City & Guilds Level 2 NVQ Certificate in Pharmacy Service Skills.

Existing City & Guilds centres not currently offering the Level 2 NVQ in Pharmacy Services and wishing to offer this qualification must use the **standard** Qualification Approval Process.

2.1 Resource requirements

Human resources

Staff delivering this qualification must be able to demonstrate that they meet the following occupational expertise requirements. They should:

- Be technically competent in the area for which they are delivering training and/or have experience of providing training. This knowledge must be at least to the same level as the training being delivered
- have recent relevant experience in the specific area they will be assessing
- have credible experience which is clearly demonstrable through continuing learning and development

Centre staff may undertake more than one role, e.g. tutor and assessor or internal verifier, but must never internally verify their own assessments.

Assessors and internal verifiers

Assessors must:

- be a registered and practising Pharmacist or a practising Pharmacy Technician who is competent in the area of practice to which the NOS units being assessed apply
- other than in Northern Ireland, pharmacy technicians must be registered or eligible to register with the Pharmacy regulator. Within Great Britain, unregistered Pharmacy Technicians who are eligible to register can only act as assessors during the transitional registration period
- hold or be working towards the appropriate Assessor qualification as identified by the qualifications regulators. Assessors holding older 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.

Internal Verifiers must:

- be a registered and practising Pharmacist or a practising Pharmacy Technician
- other than in Northern Ireland, pharmacy technicians must be registered or eligible to register with the Pharmacy regulator. Within Great Britain, unregistered Pharmacy Technicians who are eligible to register can only act as verifiers during the transitional registration period

- It is crucial that internal verifiers 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), and the requirements of national standards 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 verification roles as defined by the relevant national occupational standard
- hold or be working towards the appropriate Internal Verifier qualifications as identified by the qualifications regulators. Internal verifiers holding older qualifications must be able to demonstrate that they are assessing to current standards.
- have undertaken the appropriate assessor qualification identified by the regulator and practised as an assessor prior to undertaking the IV role.

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

Expert Witnesses

The use of expert witnesses 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 candidate in meeting the NOS identified in any given unit. This evidence must directly relate to candidate's performance in the work place which has been seen by the expert witness.

The expert witness must be either:

- a registered and practising Pharmacist or a practising Pharmacy Technician who is competent in the area of practice to which the NOS unit being assessed apply;
- other than in Northern Ireland, be registered or eligible to register with the Pharmacy regulator. Within Great Britain, unregistered Pharmacy Technicians who are eligible to register can only act as expert witnesses during the transitional registration period.

The expert witness must have:

- a working knowledge of NOS unit for the competences on which their expertise is based
- credible experience which is clearly demonstrable through continuing learning and development.

All expert witnesses must be inducted by the centre so that they are familiar with the standards for those units for which they are to provide expert witness evidence.

They must also understand the centre's recording requirements and will need guidance on the skills required to provide evidence for the NOS.

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 evidence.

Observation meeting the requirement in the qualification for observation of performance can only be undertaken by assessor and expert witnesses.

Co-ordinating Assessors 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 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 verifiers to ensure standardised practice and judgments within the assessment process

External verifiers

External verifiers must:

- be a registered and practising Pharmacist or a practising Pharmacy Technician
- other than in Northern Ireland, be registered or eligible to register with the Pharmacy regulator. Within Great Britain, unregistered Pharmacy Technicians who are eligible to register with the Pharmacy regulator can only act as external verifiers during the transitional registration period.
- have working knowledge of pharmacy and/or GP dispensing settings, the regulation, legislation and codes of practice for the service (where applicable), and the requirements of national standards 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 verifiers holding older qualifications must be able to demonstrate that they are assessing to current standards
- External verifiers who are not yet qualified against the appropriate competences but have the necessary occupational competence and experience, can be supported by a qualified external verifier who does not necessarily have the occupational expertise or experience.
- have credible experience which is clearly demonstrable through continuing learning and development.

Assessment Centres

Assessment centres will be responsible for maintaining up-to-date information on assessors, internal verifiers and expert witnesses and for ensuring the currency of the competence of internal verifiers and all those involved in the assessment process.

Continuing professional development (CPD)

Centres are expected to support their staff in ensuring that their knowledge remains current of the occupational area and of best practice in delivery, mentoring, training, assessment and verification, and that it takes account of any national or legislative developments.

2.2 Candidate entry requirements

Candidates should not be entered for a qualification of the same type, content and level as that of a qualification they already hold.

There are no formal entry requirements for candidates undertaking this qualification. However, centres must ensure that candidates have the potential and opportunity to gain the qualification successfully.

Age restrictions

This qualification is not approved for use by candidates under the age of 16, and City & Guilds cannot accept any registrations for candidates in this age group.

3 Course design and delivery

3.1 Initial assessment and induction

Centres will need to make an initial assessment of each candidate prior to the start of their programme to ensure they are entered for an appropriate type and level of qualification.

The initial assessment should identify:

- any specific training needs the candidate has, and the support and guidance they may require when working towards their qualification[s]. This is sometimes referred to as diagnostic testing.
- any units the candidate has already completed, or credit they have accumulated which is relevant to the qualification they are about to begin.

City & Guilds recommends that centres provide an induction programme to ensure the candidate fully understands the requirements of the qualification they will work towards, their responsibilities as a candidate, and the responsibilities of the centre. It may be helpful to record the information on a learning contract.

3.2 Recommended delivery strategies

Centre staff should familiarise themselves with the structure, content and assessment requirements of the qualification before designing a course programme.

Centres may design course programmes of study in any way which:

- best meets the needs and capabilities of their candidates
- satisfies the requirements of the qualification.

When designing and delivering the course programme, centres might wish to incorporate other teaching and learning that is not assessed as part of the qualification. This might include the following:

- literacy, language and/or numeracy
- personal learning and thinking
- personal and social development
- employability

Where applicable, this could involve enabling the candidate to access relevant qualifications covering these skills.

4 Assessment

4.1 Summary of assessment methods

For this qualification, candidates will be required to complete the following assessment:

- a portfolio of evidence for **each** unit.

Evidence of candidates' performance will be drawn primarily from work activities that take place under normal working conditions in a normal work environment. Evidence of performance is expected in all Units of the qualification.

There is one main evidence requirement:

1. Direct observation of practice by:
    - a qualified assessor or
    - an expert witness

Other assessment methods may include:

- simulation (see below)
- direct questioning and assignments
- assessment of products
- APEL and APL
- candidate's reflective accounts and personal statements
- evidence by a witness testimony
- professional discussion

Direct Observation

Evidence should be gathered wherever possible from naturally occurring evidence collected in the work place. Knowledge to support performance should be based on practice evidence and reflection.

Direct observation by the assessor and /or expert witness evidence is to be an evidence requirement for every unit.

Where expert witness evidence has been used solely to evidence candidate performance in a unit the assessor must carry out a professional discussion to ensure the assessor's final assessment decision is robust.

Witness Testimony

The use of witnesses is encouraged as a contribution to the provision of performance evidence presented for assessment. Witnesses are an important source of performance evidence in the workplace.

Witness Testimony is a statement or comment by someone who was present while the candidate was carrying out an activity (e.g. a colleague who does not have the necessary occupational competence to be classed as an expert witness).

Evidence from witnesses must meet the tests of validity, reliability and authenticity.

The requirements of expert witnesses are distinct and set out in 2.3.3

Professional discussion
It is a requirement that professional discussion, of which a record has been made, between the assessor and the candidate must take place when direct observation by an assessor is not possible.

Professional Discussion is a discussion which is planned and led by the assessor and must be recorded in such a way as to create an audit trail. It is not a question and answer session, but more of a chance for wider ranging discussions reflecting and evaluating on areas decided during the planning process.
Professional discussion provides a holistic approach to assessing knowledge and understanding and is useful in determining not only what and how a candidate is performing, but also their analytical and decision-making abilities.

Simulations
The use of simulation is normally only permitted in the following units but must not be the sole source of performance evidence in that particular unit:

- Pharm 11-Prepare extemporaneous medicines for individuals use
- Pharm 15- Assist in the issuing of pharmaceutical stock (unit 010)
- HSS1- Ensure your own actions reduces risks to health and safety. (unit 002)

The use of simulations in other units is only permitted in circumstances specified within unit guidance and should only be undertaken in the minority of cases ie: where performance is critical and:

- where events either never or infrequently occur and yet a high degree of confidence is needed that the candidate would act appropriately for example:
  (i) where there is a high risk of harm or abuse to the individuals, key people in their lives and others
  (ii) where events such as medical emergencies (such as cardiac arrest) occur and competence is vital to ensure best practice and results
  (iii) where cash is being handled when this does not happen routinely in the workplace or

- where events happen frequently but where there is risk of harm to the candidate or service user in a real situation, for example, dealing with aggressive or abusive situations (although evidence from direct observation should be used where possible).

Where simulations are used they must replicate working activities in realistic (but not necessarily actual) workplace environments and this must be agreed with the External Verifier beforehand

Knowledge
The Pharmacy Services NOS describe the knowledge and understanding required to support competent performance on the workplace. The awarding bodies through their external verification arrangements are responsible for ensuring that all centres make provision for candidates to successfully cover the knowledge requirements. It is expected that when a centre applies to an awarding body to offer a qualification they will identify how the knowledge will be delivered and assessed, so that the external verifiers can ensure the knowledge is adequately covered.

4.2 Recording forms

Candidates and centres may decide to use a paper-based or electronic method of recording evidence.
Amendable (MS Word) versions of the forms are available on the City & Guilds website

Although it is expected that new centres will use these forms, centres may devise or customise alternative forms, which must be approved for use by the external verifier, before they are used by candidates and assessors at the centre.

City & Guilds endorses several ePortfolio systems. Further details are available at:
www.cityandguilds.com/eportfolios.

5 Units

Availability of units

The units for this qualification follow.

They may also be obtained from the centre resources section of the City & Guilds website.

The learning outcomes and assessment criteria are also viewable on the Register of Regulated Qualifications at **register.ofqual.org.uk**

Structure of units

The units in this qualification are written in a standard format and comprise the following:

- City & Guilds reference number
- unit accreditation number
- title
- level
- credit value
- unit aim
- relationship to NOS, other qualifications and frameworks
- endorsement by a sector or other appropriate body
- information on assessment
- learning outcomes which are comprised of a number of assessment criteria
- notes for guidance.

Unit 201 Assist with the provision of a pharmacy service to meet individuals' needs

Level: **2**
Credit value: **3**

Unit aim
The aim of this unit is to provide candidates with the knowledge and skills needed to deal with individuals' needs and provide information and advice to satisfy their requirements. The unit also focuses on how to deal with instances of day-to-day complaints.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Identify individual's needs
2. Provide information which meets the requirements of the individual
3. Resolve individual's issues and concerns
4. Comply with organisational standard operating procedures, policies and procedures
5. Work within the limitations of the job role

Guided learning hours
It is recommended that **10** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards
This unit is linked to: 'Assist with the provision of a pharmacy service to meet individual needs' Pharm 01.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 201 Assist with the provision of a pharmacy service to meet individuals' needs

Outcome 1 Identify individual's needs

Assessment Criteria

The learner can:

1. deal with **individuals** promptly when working in **different situations**
2. respond to the **verbal and non verbal forms of communication** offered by the individual
3. identify the **needs of individuals** accurately through questioning
4. confirm understanding of the individual's requirements
5. agree an outcome with the individual regarding delivery of products or services.

Range

a. **Individuals:** could include; someone from another department who is not part of your team, people from outside your organisation, including: patients, patient's representatives, other healthcare staff
b. **Different situations:** could include; busy periods, quiet periods, when systems or resources are not available
c. **Verbal and non verbal forms of communication:** could include; satisfied, anxious, angry, upset
d. **Needs of the individuals:** could include; information, products, services

Unit 201 Assist with the provision of a pharmacy service to meet individuals' needs

Outcome 2 Provide information which meets the requirements of the individual

Assessment Criteria

The learner can:

1. respond to requests for **information** from individuals politely and promptly
2. provide relevant information in a **format** that the individual can understand
3. check that the information given meets the needs of the individual.

Range

a. **Information:** could include; information about symptoms, information about products, healthcare advice, available services
b. **Format:** could include; written format, oral, electronic, by telephone

Unit 201 Assist with the provision of a pharmacy service to meet individuals' needs

Outcome 3 Resolve individual's issues and concerns

Assessment Criteria

The learner can:

1. acknowledge receipt of a **query or complaint**
2. assess the **action** required to resolve the **query or complaint**
3. take action to resolve a **query/complaint** in line with **Standard Operating Procedures (SOPs)** and organisational policies for customer service
4. explain when complaints should be referred to a higher authority
5. make a record of own actions, if appropriate, taking account of **Standard Operating Procedures (SOPs)**

Range

a. **Queries/complaints:** could include; product related, service related

b. **Action:** could include; identify available options, agree an outcome, refund/credit the purchase price, replace goods, referral

c. **Standard operating procedures (SOPs)**: could include; basics of current legislation, regulations and practice of industry, organisation, professional and ethical standards for pharmacy service queries and complaints

Unit 201 Assist with the provision of a pharmacy service to meet individuals' needs

Outcome 4 Comply with organisational standard operating procedures, policies and procedures

Assessment Criteria

The learner can:

1. adhere to **Standard Operating Procedures (SOPs)** at all times
2. describe the importance of maintaining customer satisfaction, loyalty and confidence in the organisation
3. contribute to the **organisation's policy** on customer service.

Range

a. **Standard operating procedures (SOPs)**: could include; basics of current legislation, regulations and practice of industry, organisation, professional and ethical standards for pharmacy customer service provision

b. Organisation's policy: could include; local policies or procedures, protocols on customer loyalty, handling complaints and managing potential conflict regarding pharmacy services provision

Unit 201 Assist with the provision of a pharmacy service to meet individuals' needs

Outcome 5 Work within the limitations of the job role

Assessment Criteria

The learner can:

1. refer the individual to an **appropriate person** when providing information and advice is outside the limits of own responsibility
2. explain to the individual the action/s taken and why
3. identify relevant sources of information individuals can access
4. state the types of information that can be given to individuals by themselves
5. state the types of information that should be given to individuals by the pharmacist.

Range

a. **Appropriate person:** could include; manager, supervisor, senior pharmacy technician, pharmacist

Unit 202 Ensure your own actions reduce risks to health and safety

Level: 2
Credit value: 2

Unit aim
This unit is about health and safety in your day to day work. This includes identifying and dealing with risks and hazards in your workplace.

Learning outcomes
There are **three** learning outcomes to this unit. The learner will be able to:
1. Identify the hazards in the workplace
2. Act upon hazards in the workplace
3. Reduce the risks to health and safety in their workplace

Guided learning hours
It is recommended that **8** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards
This unit is linked to the NOS HSS1.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- portfolio containing examples of observed practice in the learner's workplace.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will be accepted for those learning outcomes where evidence does not occur as part of real work activities and specifically for learning outcome 2 where no hazards arise.

Unit 202 Ensure your own actions reduce risks to health and safety

Outcome 1 Identify the hazards in the workplace

Assessment Criteria

The learner can:

1. identify which workplace procedures are relevant to your job
2. identify those working practices in your job which could harm you or others
3. identify those aspects of your **workplace** which could harm you or others
4. outline any differences between **workplace legislation** and suppliers or manufacturer's instructions.

Range

a. **Workplace:** could be your pharmacy or area of work

b. **Workplace legislation**: could include; Standard Operating Procedures (SOPs),health and safety legislation, machinery operating instructions, use of materials, medicines and raw materials, finished products, packaging

Unit 202 Ensure your own actions reduce risks to health and safety

Outcome 2 Act upon hazards in the workplace

Assessment Criteria

The learner can:

1. report hazards to the identified **responsible person**
2. demonstrate the ability to deal with **hazards** in the **workplace**.

Range

a. **Responsible person**: could include; your manager, section leader or the health and safety person in your workplace
b. **Hazards**: could include; spills, trips, breakages, obstructions, faulty equipment or machinery, environmental factors, incorrect storage of medicines or raw materials
c. **Workplace**: could be your pharmacy or area of work

Unit 202 Ensure your own actions reduce risks to health and safety

Outcome 3 Reduce the risks to health and safety in their workplace

Assessment Criteria

The learner can:

1. carry out your work in accordance with **workplace legislation** or manufacturer's instructions
2. behave in a way that does not endanger the health and safety of yourself, others and materials in your **workplace**
3. contribute to health and safety improvements within your workplace
4. follow guidelines for environmentally friendly **working practices**
5. ensure personal presentation protects the health and safety of you or others in line with instructions.

Range

a. **Workplace legislation:** could include; Standard Operating Procedures (SOPs), health and safety legislation, protocols and policies, machinery operating instructions, use of materials, medicines and raw materials, finished products

b. **Workplace**: could be your pharmacy or area of work

c. **Workplace practices:** could include; legislation, policies and Standard Operating Procedures (SOPs)

Unit 203 Contribute to the effectiveness of teams

Level: **2**
Credit value: **3**

Unit aim
The aim of this unit is to introduce candidates to the skills and knowledge that will ensure that they contribute to the effectiveness of teams. The unit also addresses time management, legislations and policies.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Explain the importance of own role and how it contributes to the team performance
2. Use feedback to improve personal team performance
3. Manage time and commitments effectively
4. Establish effective working relationships with all members of the team
5. Comply with organisational, National and European legislation

Guided learning hours
It is recommended that **5** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards
This unit is linked to: 'Contribute to effectiveness of teams' HSC241.

Endorsement of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment and grading
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 5**
Simulation will be accepted for learning outcome 4 where no differences of opinion or conflicts arise.

Unit 203 Contribute to the effectiveness of teams

Outcome 1 Explain the importance of own role and how it contributes to the team performance

Assessment Criteria

The learner can:

1. describe the **team's** overall objectives and purpose
2. explain how own role and responsibilities contribute to team activities, objectives and purposes
3. identify other team members, their roles and responsibilities within the team
4. inform other members in the team of their activities and ideas.

Range

a. **Team's:** could include; work team, a multidisciplinary team, broader multi agency team

Unit 203 Contribute to the effectiveness of teams

Outcome 2 Use feedback to improve personal team performance

Assessment Criteria

The learner can:

1. use **feedback** or suggestions from others to enable them to improve own practice within the team
2. propose suggestions or ideas to benefit team members and improve team working
3. agree, seek support and take responsibility for any development and learning that can help you to interact with the team more effectively.

Range

a. Feedback: could include; written or verbal, appraisals, review meeting, personal development plans, team meetings

Unit 203 Contribute to the effectiveness of teams

Outcome 3 Manage time and commitments effectively

Assessment Criteria

The learner can:

1. fulfil own **commitments** to other team members within agreed timescales and according to overall work priorities
2. inform appropriate team members when they cannot fulfil **commitments** within specified timescales.

Range

a. **Commitments:** could include; daily work schedules, specific work tasks, rota, rest breaks, urgent work

Unit 203 Contribute to the effectiveness of teams

Outcome 4 Establish effective working relationships with all members of the team

Assessment Criteria

The learner can:

1. **behave** towards other team members in a way that supports the effective functioning of the team
2. resolve **differences of opinion and conflicts** within the team in ways which respects other team members' points of view
3. select **appropriate advice and guidance** in order to resolve issues with other team members
4. support other team members in the completion of activities or objectives.

Range

a. **Behave:** could include; verbal and non verbal communication, sharing tasks, covering others work commitments

b. **Differences of opinion and conflicts:** could include; verbal and non verbal communication, written communication, work tasks

c. **Appropriate advice and guidance:** could include; information from manager, supervisor, senior pharmacy technician, organisational policies and procedures, legislation for working effectively as a team, barriers to effective working and handling problems within the team

Unit 203 Contribute to the effectiveness of teams

Outcome 5 Comply with organisational, National and European legislation

Assessment Criteria

The learner can:

1. comply with **legal and organisational requirements**, standards and codes of practice on equality, diversity, discrimination and rights relevant to own role and responsibilities.
2. comply with current local, UK and European **legislation, and organisational requirements**, procedures and practices
3. access up-to-date copies of the organisation's workplace policies, procedures and systems, and practice and service standards related to team working.

Range

a. **Legislation, and organisational requirements:** could include**;** basics of current pharmacy legislation, protocols, regulations and practice of industry, organisation, professional and ethical standards, health and social legislation (data protection, confidentiality, equal opportunities) and learning and development opportunities

Unit 204 Assist in the sale of medicines and products

Level: 2
Credit value: 8

Unit aim
This unit enables the learners to competently sell over the counter medicines and products in a pharmacy setting.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Identify customers' needs
2. Refer a customer to the appropriate authority
3. Understand when the sale of OTC medicines cannot be completed
4. Sell medicines or products
5. Know the local policy, legislation and good practice for sale of medicines

Guided learning hours
It is recommended that **50** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards
This unit is linked to the Pharm 05.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: 1**, 2, 4, 5**
Simulation will be accepted for learning outcome 3 where no requests for excessive or regular quantities of medicines that are liable to abuse or misuse occur

Unit 204 Assist in the sale of medicines and products

Outcome 1 Identify customers' needs

Assessment Criteria

The learner can:

1. acknowledge **customers** promptly and politely
2. use appropriate **questioning techniques** to ascertain **customer** requirements.

Range

a. **Customers:** could include**;** those with a general idea, those with special needs, those with a clear idea, customer representatives

b. **Questioning techniques:** could include; 2WHAM questions, open and closed questions

Unit 204 Assist in the sale of medicines and products

Outcome 2 Refer a customer to the appropriate authority

Assessment Criteria

The learner can:

1. identify when to refer to an **appropriate authority**
2. refer customers who request medicines with the same active ingredient or with similar action to an appropriate authority
3. give relevant information to the **appropriate person** about the referral
4. describe how to deal with different **individuals**.

Range

a. **Appropriate authority**: could include; a pharmacist or prescriber

b. **Appropriate person:** could include; a pharmacist, prescriber, pharmacy technician

c. **Individuals**: could include; those asking for themselves, those asking on behalf of others, those with a general idea, a clear idea ,with special needs or those with no idea of their needs

Unit 204 Assist in the sale of medicines and products

Outcome 3 Understand when the sale of OTC medicines cannot be completed

Assessment Criteria

The learner can:

1. inform the pharmacist when a customer requests excessive or regular quantities of **medicines that are liable to abuse or misuse**
2. explain to the customer when the sale of medicines cannot be completed.

Range

a. **Medicines that are liable to abuse or misuse :** could include; pain killers, opiate pain killers (codeine etc), stimulants (ephedrine/pseudoephedrine), cough medicines, laxatives, sleep aids, products containing solvents (PR Spray etc)

Unit 204 Assist in the sale of medicines and products

Outcome 4 Sell medicines or products

Assessment Criteria

The learner can:

1. offer customers a choice of **medicines or products** to meet their requirements
2. provide **information and advice** to the customer regarding the medicines or products
3. pack medicines or products appropriately
4. take payment according to organisational policies.

Range

a. **Medicines or products:** could include; general sales list (GSL), pharmacy only (PO) , pharmacy medicines (P)

b. **Information and advice**: could include; suitable information to give to individuals, main actions and uses, side effects of main ingredients within commonly used non-prescription medicines, written or oral information, patient information leaflets (PILs), healthcare leaflets and pack information to assist individuals, information from manufacturer, and information from other healthcare providers

Unit 204 Assist in the sale of medicines and products

Outcome 5 Know the local policy, legislation and good practice for sale of medicines

Assessment Criteria

The learner can:

1. list different **sources of information** suitable for customers
2. state why it is important that **Standard Operating Procedures** must be followed at all times
3. state why it is important that the **pharmacy protocol** is followed at all times.

Range

a. **Sources of Information**: could include; written, electronic, patient information leaflets, manufacturers information

b. **Standard operating procedures (SOPs)**: could include; basics of current pharmacy legislation, protocols, regulations and practice of industry, organisation, professional and ethical standards, health and social legislation (data protection, confidentiality, equal opportunities) for assisting in the sale of medicines and products

c. **Pharmacy Protocol**: could include; procedures for supplying a medicine or giving advice on treatment of a medical condition sought, pharmacist sales list, high risk medicines

Unit 305 Receive prescriptions from individuals

Level: **3**
Credit value: **3**

Unit aim
This unit introduces candidates to the working in the dispensary reception area of a pharmacy. Candidates will be expected to apply basic legislation and local requirements to the assessment of prescription to ensure they are suitable for dispensing and manage the interaction with individuals effectively. The aim of this unit is to provide the candidate with skills and knowledge needed to effectively receive and process prescriptions that are presented at the pharmacy before they are passed on to the dispensing process.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Ensure that the prescription declaration is complete
2. Complete financial transaction procedures
3. Provide the individual with relevant information
4. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
5. Operate within the limitations of the job role

Guided learning hours
It is recommended that **15** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards
This unit is linked to: 'Receive prescriptions from individuals' Pharm 07.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 305 Receive prescriptions from individuals

Outcome 1 Ensure that the prescription declaration is complete

Assessment Criteria

The learner can:

1. greet the **individual** politely, promptly, maintaining privacy and confidentiality throughout
2. demonstrate how to deal with individuals with **special needs**
3. check that the patient details are clear, correct and complete
4. check that the patient declaration of the prescription has been completed
5. examine evidence of exemption where appropriate
6. state the different types of prescribers including the **types of prescriptions** used
7. check that the prescription is **legally valid**
8. issue a prescription receipt following local **Standard Operating Procedures (SOPs)** .

Range

a. **Individual:** could include; the patient, their representative or someone involved in their care

b. **Special needs**: could include; those who have special educational needs and physical needs, individuals with urgent prescriptions, mothers with young children, individuals whose first language is not English

c. **Types of prescriptions**: could include; paper based, electronic, NHS, private, veterinary, for clinical trials

d. **Legally valid**: includes; meets the requirements of all current legislation regarding prescriptions

e. **Standard operating procedures (SOPs)**: could include; basics of current pharmacy legislation, protocols, regulations and practice of industry, organisation, professional and ethical standards, health and social legislation (data protection, confidentiality, equal opportunities) for receiving prescriptions

Unit 305 Receive prescriptions from individuals

Outcome 2 Complete financial transaction procedures

Assessment Criteria

The learner can:

1. explain exemption and **appropriate prescription charge requirements**
2. complete a **financial transaction procedure**.

Range

a. **Appropriate prescription charge requirements:** could include; different prescription charging frameworks in different countries, multiple charge items, exemptions, prescription charge prepayment certification, refunds, issue of official receipts and reclaim forms, advise where items might be purchased

b. **Financial transaction procedure:** could include; using cash, cheque, credit card to pay prescription charges where appropriate, issue of official receipts, official reclaim forms or prescription receipts (i.e. numbered tickets), prepaid certificates, costing of private prescriptions including VAT

Unit 305 Receive prescriptions from individuals

Outcome 3 Provide the individual with relevant information

Assessment Criteria

The learner can:

1. manage individual's expectations for waiting or collection times
2. discuss potential **product availability problems**
3. discuss alternative delivery services
4. complete any required **dispensary records**
5. forward prescription for validation and dispensing.

Range

a. **Product availability problems**: could include; out of stock, out of stock from suppliers, insufficient quantity, options for providing stock to the patient

b. **Dispensary records:** could include paper based, or electronic records

Unit 305 Receive prescriptions from individuals

Outcome 4 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. explain **current ethical and legal requirements** that affect prescriptions, including relating to clinical trials
2. operate in accordance with the **Standard Operating Procedures (SOPs)** at all times
3. access relevant national and local guidelines and policies and procedures.

Range

a. **Current ethical and legal requirements:** could include; current pharmacy legislation, types of prescribers, classification of medicines , prescription charges, prescription legal validity, professional and ethical standards, health and social legislation e.g. data protection, confidentiality, equal opportunities

b. **Standard operating procedures (SOPs**): could include; regulations and practice of industry, organisational, transactional and administration procedures and records

Unit 305 Receive prescriptions from individuals

Outcome 5 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. work within the scope of responsibility and practice
2. understand the limitations of your scope of practice and when to refer to an **appropriate person**.

Range

a. **Appropriate person:** could include; a pharmacist or prescriber, senior colleague, pharmacy technician

Unit 206 Assemble prescribed items

Level: **2**
Credit value: **3**

Unit aim
The aim of this unit is to provide the candidate with the skills needed to assemble prescribed items accurately and safely whilst applying knowledge of the legal, ethical and health and safety requirements that affect this activity.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Prepare to assemble prescribed items
2. Select the prescribed item
3. Label and package prescribed items
4. Complete the assembly process
5. Comply with current legal and ethical requirements, organisational standard operating procedures and relevant national and local guidelines and policies

Guided learning hours
It is recommended that **15** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards
This unit is linked to: 'Assemble prescribed items' Pharm 09.

Endorsement of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment and grading
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 206 Assemble prescribed items

Outcome 1 Prepare to assemble prescribed items

Assessment Criteria

The learner can:

1. follow the relevant health, hygiene and safety procedures
2. ensure that the preparation area and equipment are clean and maintained ready for use
3. produce the correct label
4. ensure that there is an adequate supply of **items** to assist in the supply of medicines.

Range

a. **Items:** could include; bottles, containers, bags and sundry items

Unit 206 Assemble prescribed items

Outcome 2 Select the prescribed item

Assessment Criteria

The learner can:

1. confirm that the **medicine or product** is **fit for purpose**
2. confirm that the medicine or product matches the prescription
3. prepare medicine or product following **Standard Operating Procedures (SOPs)**
4. refer to the **appropriate person** where there are **inconsistencies** in the medicine or product.

Range

a. **Medicine or product:** could include**;** solid forms (tablets, capsules, pessaries, suppositories), liquid forms (oral, topical, injectable), preparations to be taken internally, preparations to be used externally, original packs, reconstitution e.g. antibiotics, cytotoxics

b. **Fit for purpose:** could include; intact, presentable packaging, clean, non-contaminated packaging, within the expiry date

c. **Standard operating procedures (SOPs)**: could include; basics of current legislation, regulations and practice of industry, organisational, professional and ethical standards, for labelling and assembling medicines

d. **Appropriate person:** could include; pharmacist, prescriber, other healthcare professional, senior colleague, pharmacy technician

e. **Inconsistencies:** could include; expiry date, insufficient stock, insufficient stock of specific strengths, to-follows

Unit 206 Assemble prescribed items

Outcome 3 Label and package prescribed items

Assessment Criteria

The learner can:

1. assemble prescribed items according to the correct instructions and reconstitute items as required
2. label the item correctly, checking it against the prescription
3. pack the **medicine or product** using appropriate packaging
4. select appropriate **medicine devices/sundry items** to accompany the medicine or product.

Range

a. **Medicine or product:** could include; solid forms (tabs, caps etc), liquid forms (oral, topical, injectable), preparations to be internally, preparations to be used externally, original packs, reconstitution e.g. antibiotics, cytotoxics.

b. **Medicine devices/sundy items:** could include; spoons, measuring cups, oral syringes and bungs, pill splitters/cutters, inhaler-aids

Unit 206 Assemble prescribed items

Outcome 4 Complete the assembly process

Assessment Criteria

The learner can:

1. annotate the prescription/requisition appropriately
2. complete **dispensary records** legibly and accurately
3. forward the prescription and assembled items for checking as identified in the **Standard Operating Procedures (SOPs)**.

Range

a. **Dispensary records:** could include; paper based, electronic records

b. **Standard Operating Procedures (SOPs)**: could include; protocols, regulations and practice of industry, organisation, professional and ethical standards for endorsing prescriptions and dispensary records

Unit 206 Assemble prescribed items

Outcome 5 Comply with current legal and ethical requirements, organisational standard operating procedures and relevant national and local guidelines and policies

Assessment Criteria

The learner can:

1. understand the basics of **current legal and ethical requirements** that affect the assembly of prescribed items
2. apply knowledge of organisational **Standard Operating Procedures (SOPs)** when assembling prescribed items
3. apply knowledge of national and local guidelines and policies for assembling prescribed items
4. work within the limitations of your own role recognising when to refer to an appropriate person.

Range

a. **Current legal and ethical requirements:** could include; basics of current pharmacy legislation, professional and ethical standards, health and social legislation e.g. data protection, confidentiality, equal opportunities that governs assembly of prescribed items
b. **Standard Operating Procedures (SOPs):** could include; protocols, regulations and practice of industry, organisation, professional and ethical standards for prescribing abbreviations, generic and proprietary medicines, handling hazardous medicines, dispensing equipment, labelling requirements, container and packaging requirements, patient information leaflets, storage requirements, expiry of medicines, dispensing sterile products, prescription endorsement and dispensing records

Unit 207 Order routine pharmaceutical stock

Level: **2**
Credit value: **3**

Unit aim
The learner will be able to identify ordering requirements, accurately completing all necessary documentation.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Accurately order stock
2. Process orders
3. Complete the ordering process
4. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
5. Operate within the limitations of the job role

Guided learning hours
It is recommended that **11** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards
This unit is linked to the Pharm 12.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of examples from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 207 Order routine pharmaceutical stock

Outcome 1 Accurately order stock

Assessment Criteria

The learner can:

1. accurately identify pharmaceutical **stock requirements**
2. **place an order** for identified stock
3. confirm order is correct
4. apply knowledge of the difference between branded and generic drugs.

Range

a. **Stock requirements**: could include; stock levels, reorder quantities, urgent orders, seasonal variations

b. **Place an order**: could include; written, electronic, telephone, fax

Unit 207 Order routine pharmaceutical stock

Outcome 2 Process orders

Assessment Criteria

The learner can:

1. request **checks on orders** when required
2. correctly **process orders**
3. report any problems to the **appropriate person**.

Range

a. **Check on orders**: could include; stock availability, stock shortages, stock adjustments, pack sizes
b. **Process orders:** could include**;** electronic, paper, telephone, fax
c. **Appropriate person:** could include**;** other healthcare professionals, pharmacy staff, customers

Unit 207 Order routine pharmaceutical stock

Outcome 3 Complete the ordering process

Assessment Criteria

The learner can:

1. maintain all **documentation** appropriately
2. check the progress of outstanding orders.

Range

a. **Documentation:** could include; electronic or paper

Unit 207 Order routine pharmaceutical stock

Outcome 4 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. demonstrate working in accordance with the **Standard Operating Procedures** at all times
2. explain the importance of following **Standard Operating Procedures (SOPs)** when **ordering stock**
3. demonstrate compliance with **legal, professional and organisational requirements**, guidelines and confidentiality at all times.

Range

a. **Standard Operating Procedures:** could include; regulations and practice of industry, organisational, professional and ethical standards for ordering stock

b. **Ordering stock:** could include; stock levels, reorder quantities, urgent orders, seasonal variations

c. **Legal, professional and organisational requirement :** could include; basics of current pharmacy legislation, pharmacy contracts awareness, financial information, good distribution practice that governs ordering stock

Unit 207 Order routine pharmaceutical stock

Outcome 5 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. explain the limits of your own authority
2. report any problems to the **appropriate person**.

Range

a. **Appropriate person**, could include; other healthcare professionals, pharmacy staff, customers

Unit 311 Receive pharmaceutical stock

Level: **3**
Credit value: **3**

Unit aim
This unit enables learners to receive and store pharmaceutical stock. This unit requires learners to show that they understand current legislation and good practice when receiving pharmaceutical stock.

Learning outcomes
There are **six** learning outcomes to this unit. The learner will be able to:
1. Receive stock
2. Correctly store stock
3. Complete the receipt of stock
4. Know about the current legislation and good practice for receipt of stock
5. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
6. Operate within the limitations of the job role

Guided learning hours
It is recommended that **9** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards
This unit is linked to the Pharm 13

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 311 Receive pharmaceutical stock

Outcome 1 Receive stock

Assessment Criteria

The learner can:

1. confirm deliveries against delivery notes and the original order
2. apply knowledge of the difference between branded and generic drugs
3. identify any **discrepancies** and **delivery problems**
4. take **appropriate action** to remedy any discrepancies and delivery problems
5. sign for received order, when stock is **fit for purpose**.

Range

a. **Discrepancies:** could include; incorrect item, formulation, strength, quantity, pack size, expired, short dated, damaged, broken, etc
b. **Delivery problems:** could include; discrepancies, unavailable stock, missing stock, wrong address
c. **Appropriate action**: could include; reorder stock, remove stock and reporting stock issues to a supervisor
d. **Fit for purpose**: could include; intact, presentable packaging, clean non-contaminated packaging and within expiry date

Unit 311 Receive pharmaceutical stock

Outcome 2 Correctly store stock

Assessment Criteria

The learner can:

1. store stock safely in **correct storage location**
2. identify **special storage requirements** for received stock
3. store stock according to stock rotation procedures
4. describe the importance of placing received stock in a **safe storage environment.**

Range

a. **Storage location:** could include; refrigerator, secured area, room temperature, ventilated area and isolated area

b. **Special storage requirements:** could include; low temperature, room temperature, special orders ,raw materials, cytotoxics, clinical trials products

c. **Safe storage environment:** could include; stock stored safely, refrigerators in working order, walkways free from obstacles

Unit 311 Receive pharmaceutical stock

Outcome 3 Complete the receipt of stock

Assessment Criteria

The learner can:

a. notify the **appropriate person** of the **change in the availability of stock**

b. complete all relevant **documentation** records accurately

c. process the documentation promptly.

Range

a. **Appropriate person:** could include; the supplier, pharmacist, pharmacy technician, supervisor, prescriber, and other healthcare professional

b. **Change in the availability of stock**: could include; stock not on the original order, is not the complete order, beyond expiry date, has inconsistent batch number or has batch number for which drug alerts, recalls have been issued and stock is damaged or contaminated

c. **Documentation**: could include; input and retrieval of stock data, paper or electronic, back up IT systems

Unit 311 Receive pharmaceutical stock

Outcome 4 Know about the current legislation and good practice for receipt of stock

Assessment Criteria

The learner can:

1. describe the importance of following **Standard Operating Procedures** related to receiving stock
2. state the different formulations, strengths and forms of medications available
3. discuss the differences between generic and branded medications
4. demonstrate knowledge of local ordering systems including sources and suppliers of stock
5. follow current health and safety legislation in relation to moving and handling received stock
6. demonstrate a working knowledge of local or regional pharmaceutical contracts.

Range

a. Standard Operating Procedures: could include; basics of current legislation, regulations and practice of industry, organisation, professional and ethical standards

Unit 311 Receive pharmaceutical stock

Outcome 5 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. understand **current legislation** and your responsibilities that apply to the receipt of pharmaceutical stock
2. understand the importance of following **Standard Operating Procedures (SOPs)** related to receiving pharmaceutical stock
3. work in accordance with **Standard Operating Procedures (SOPs)** related to receiving pharmaceutical stock
4. demonstrate knowledge of the COSHH and health and safety requirements related to receipt of pharmaceutical stock.

Range

a. **Current legislation**: could include; current pharmacy legislation, professional and ethical standards that govern the receiving of pharmaceutical stock, including health and safety and processes for drug alerts and company recalls.

b. **Standard operating procedures (SOPs)**: could include; protocols, regulations and practice of industry, organisation, professional and ethical standards, local or regional pharmaceutical contracts, stock rotation, safe storage of stock, sources of suppliers, and unavailable stock.

Unit 311 Receive pharmaceutical stock

Outcome 6 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. work within the limits of your own authority
2. know when to refer to an **appropriate person**.

Range

a. **Appropriate person:** could include; supervisor, senior pharmacy technician, pharmacy staff, other healthcare professionals, customers, supplier

Unit 312 Maintain pharmaceutical stock

Level: **3**
Credit value: **3**

Unit aim
This unit enables learners to understand how to maintain pharmaceutical stock and storage areas. Learners will need to show that they can accurately carry out stock checks.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Maintain a safe storage environment
2. Carry out stock checks
3. Deal with stock related problems
4. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
5. Operate within the limitations of the job role

Guided learning hours
It is recommended that **4** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards
This unit is linked to the Pharm 14.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 312 Maintain pharmaceutical stock

Outcome 1 Maintain a safe storage environment

Assessment Criteria

The learner can:

1. carry out checks of **storage conditions** ensuring they are fit for purpose
2. take **appropriate action** in respect of problems with storage conditions.

Range

a. **Storage conditions**: could include; general areas, secure areas, isolated areas, low temperature areas and ventilated areas

b. **Appropriate action:** could include; replacement of stock, safe disposal of stock, completion of appropriate documentation and communication of relevant information

Unit 312 Maintain pharmaceutical stock

Outcome 2 Carry out stock checks

Assessment Criteria

The learner can:

1. carry out **stock checks** ensuring stock is **fit for purpose**
2. rotate stock to reduce wastage
3. check stock is available in sufficient formulations and quantity including **special orders**
4. **reconcile details** of stock checks as required
5. describe the difference between branded and generic drugs.

Range

a. **Fit for purpose**: could include; within expiry date, intact packaging and clean, non contaminated packaging

b. **Special orders**: could include; named- patient drugs, clinical trial stock, unlicensed items, non-formulary items and emergency/urgent orders

c. **Reconcile details**: could include; input and retrieval of stock data, paper or electronic, back up IT systems

Unit 312 Maintain pharmaceutical stock

Outcome 3 Deal with stock related problems

Assessment Criteria

The learner can:

1. take **the appropriate** action in respect of expired and damaged stock
2. take the appropriate action in respect of over-stock
3. promptly deal with any recalls or drug alerts following agreed guidelines
4. describe the importance of maintaining a safe storage environment
5. describe your responsibilities in relation to **current legislation** and the maintenance of stock.

Range

a. **Appropriate action**, could include; replacement of stock, safe disposal of stock, completion of appropriate documentation and communication of relevant information
b. **Current legislation**: could include; current pharmacy legislation, professional and ethical standards that govern the maintenance of pharmaceutical stock, including health and safety, control of substances hazardous to health and processes for drug alerts and company recalls

Unit 312 Maintain pharmaceutical stock

Outcome 4 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. describe the importance of following **Standard Operating Procedures (SOPs)** related to maintaining stock
2. comply with the health and safety requirements related to maintaining pharmaceutical stock and disposing of outdated, damaged or decontaminated stock
3. understand the importance of good stock management, including the quantity of stock taking account of seasonal variations.

Range

a. **Standard operating procedures (SOPs)**: could include; protocols, regulations and practice of industry, organisational, professional and ethical standards, stock levels, stock rotation, safe storage of stock, spoilt stock, disposal of stock, sources of suppliers and unavailable stock

Unit 312 Maintain pharmaceutical stock

Outcome 5 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. act within the limits of your authority when dealing with stock problems
2. refer to **appropriate person**
3. understand your responsibilities and **current legislation** that applies to maintaining pharmaceutical stock.

Range

a. Appropriate person: could include; supervisor, senior pharmacy technician, pharmacy staff, other healthcare professionals, customers, supplier

b. Current legislation: could include current pharmacy law, good distribution practice, stock rotation, specific storage requirements

Unit 210 Assist in the issuing of pharmaceutical stock

Level: 2
Credit value: 4

Unit aim
This unit will enable the learner to assist with the issue of pharmaceutical stock and know why stock must be issued correctly.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Assemble stock for issue
2. Issue stock
3. Complete the issuing process
4. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
5. Operate within the limitations of the job role

Guided learning hours
It is recommended that **5** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards (if appropriate)
This unit is linked to the Pharm 15 (level 2).

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence

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Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will **n**ot be accepted for these learning outcomes where evidence does not occur as part of real work activities.

Unit 210 Assist in the issuing of pharmaceutical stock

Outcome 1 Assemble stock for issue

Assessment Criteria

The learner can:

1. select the **requisition** of the orders
2. select the correct products for issue against a request
3. confirm that the product selected is
    - the correct drug, appliance or device
    - the correct quantity
    - the correct pack size
    - within the expiry date
    - of intact packaging
4. identify any stock that is not **fit for purpose**.

Range

a. **Requisitions:** could include: picking lists, bar codes, ward orders, assembly list, issue lists
b. **Fit for purpose:** could include; intact, clean and within expiry date

Unit 210 Assist in the issuing of pharmaceutical stock

Outcome 2 Issue stock

Assessment Criteria

The learner can:

1. issue stock including special orders and urgent requests informing the appropriate person in line with stock rotation
2. issue stock **fit for purpose**
3. take **appropriate action** if stock is not available.

Range

a. **Fit for purpose:** could include; intact, clean and within expiry date
b. **Appropriate action:** could include; notifying the person requesting the stock

Unit 210 Assist in the issuing of pharmaceutical stock

Outcome 3 Complete the issuing process

Assessment Criteria

The learner can:

1. place stock safely and securely within the **appropriate packaging**
2. **label** packaging correctly
3. issue stock to the correct **destination**
4. complete all paper and electronic **documentation** correctly.

Range

a. **Appropriate packaging:** could include: cool containers, protective containers
b. **Label:** could include: destination, warnings-fragile, heavy, cytotoxic, refrigerator items
c. **Destination:** could include: internal orders, external orders, return of goods to supplier
d. **Documentation:** could include: electronic or paper

Unit 210 Assist in the issuing of pharmaceutical stock

Outcome 4 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. comply with **current legislation** that applies to issuing pharmaceutical stock
2. describe your responsibilities under **current legislation** when issuing pharmaceutical stock
3. describe the importance of following **Standard Operating Procedures (SOPs)** related to issuing pharmaceutical stock
4. comply with health and safety requirements related to issuing pharmaceutical stock
5. describe the difference between branded and generic drugs
6. describe the importance of checking stock for issue against current drug alerts or recalls.

Range

a. **Current legislation:** could include; basics of current pharmacy legislation, professional and ethical standards that govern the issue of pharmaceutical stock, including health and safety recalls and processes for drug alerts and company recalls

b. **Standard Operating Procedures:** could include; regulations and practice of industry, organisational, professional and ethical standards, local procedures**,** stock rotation, specific storage requirements, packaging and transportation requirements, delivery methods and stock destinations

Unit 210 Assist in the issuing of pharmaceutical stock

Outcome 5 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. work within the limits of your own authority
2. refer to an **appropriate person**.

Range

a. **Appropriate person:** could include supervisor, senior pharmacy technician, pharmacy staff, other healthcare professionals, customers, supplier

Unit 211 Assist in the manufacture and assembly of medicinal products

Level: 2
Credit value: 7

Unit aim
The aim of this unit is to provide the candidate with the knowledge and skills needed to assist in the manufacture and assembly of medicinal products.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Prepare the environment, equipment, ingredients and self prior to assembly or manufacture of medicinal products
2. Assist with the preparation and processing of medicinal products
3. Complete the assembly and manufacturing process of medicinal products
4. Operate within the limitations of the job role
5. Comply with standard operating procedures, health and safety and environmental monitoring policies

Guided learning hours
It is recommended that **20** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards
This unit is linked to: 'Assist in the manufacture and assembly of medicinal products' Pharm 16.

Endorsement of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment and grading
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 211 Assist in the manufacture and assembly of medicinal products

Outcome 1 Prepare the environment, equipment, ingredients and self prior to assembly or manufacture of medicinal products

Assessment Criteria

The learner can:

1. confirm that the correct worksheet, labels, raw materials, **equipment** and consumables are available and ready for use
2. put on the appropriate protective clothing
3. follow the correct gowning procedure
4. assist with cleaning and preparing the **environmental area**
5. use the correct materials for cleaning of the environmental areas.

Range

a. **Equipment:** could include; balances, measures, mixers, pumps, filters, tablet counters, steriliser (e.g. autoclave, dry heat oven)

b. **Environmental area:** could include; laminar flow cabinets, clean room, isolators, non-sterile and sterile preparation rooms and changing rooms

Unit 211 Assist in the manufacture and assembly of medicinal products

Outcome 2 Assist with the preparation and processing of medicinal products

Assessment Criteria

The learner can:

1. assist with preparation of **products** in accordance with the batch sheet using the correct **process** and **equipment**
2. undertake all process checks at the relevant stages
3. take quality samples as appropriate
4. pack and label product
5. select and label secondary packaging
6. assist with the completion of all necessary reconciliation calculations for the product and labels
7. complete all **documentation** accurately
8. quarantine product following the final check by the **appropriate person**.

Range

a. **Products:** could include; topical fluids, intravenous products using terminal sterilization, solid dose forms (capsules, tablets, powders, suppositories), ointments and creams, emergency boxes (cardiac arrest boxes), oral mixtures/solutions

b. **Process:** could include; mixing, filtration, reconstitution, incorporation, filling, assembly, over labelling

c. **Equipment:** could include; balances, measures, mixers, pumps, filters, tablet counters, steriliser e.g. autoclave, dry heat oven

d. **Documentation:** could include; batch work sheets, batch number allocation records, environmental monitoring records e.g. air pressure differential logs, cleaning records, equipment logs, quality exception reports

e. **Appropriate person:** could include; pharmacist, pharmacy technician, supervisor

Unit 211 Assist in the manufacture and assembly of medicinal products

Outcome 3 Complete the assembly and manufacturing process of medicinal products

Assessment Criteria

The learner can:

1. ensure that all equipment is dismantled, cleaned and decontaminated
2. store or dispose of equipment correctly
3. store or dispose of **waste** correctly
4. clean and decontaminate all **environmental areas** using the correct cleaning material.

Range

a. **Waste:** could include; hazardous waste, general waste, sharps

b. **Environmental areas:** could include; laminar flow cabinets, clean room, isolators, non-sterile and sterile preparation rooms and changing room.

Unit 211 Assist in the manufacture and assembly of medicinal products

Outcome 4 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. report any defects to an appropriate person
2. report any out of specification results/**unusual events** in accordance with **Standard Operating Procedures (SOPs)**
3. take appropriate action following an unusual event, within the limits of your authority.

Range

a. **Unusual events:** could include; wastage/spills, errors, differences in resultant batch size, environmental issues, failure of equipment.

b. **Standard Operating Procedures (SOPs)**: could include; basics of current legislation, current Good Manufacturing Practice, regulations and practice of industry, organisation, professional and ethical standards for the manufacture and assembly of medicinal products.

Unit 211 Assist in the manufacture and assembly of medicinal products

Outcome 5 Comply with standard operating procedures, health and safety and environmental monitoring policies

Assessment Criteria

The learner can:

1. work in accordance with **Standard Operating Procedures (SOPs)**
2. work according to health and safety and COSHH procedures and within own limits of responsibility
3. assist in undertaking relevant **environmental monitoring** checking that the parameters, where appropriate, are within the set limits:
   a. prior to preparation
   b. during preparation
   c. following completion of preparation
4. inform the appropriate person if the **environmental parameters** are outside the set limits.

Range

a. **Standard Operating Procedures (SOPs):** could include :basics of current legislation, current Good Manufacturing Practice, regulations and practice of industry, organisation, professional and ethical standards, local procedures for the manufacture and assembly of medicinal products, including health and safety and control of substances hazardous to health (COSHH)

b. **Environmental monitoring:** could include; air pressure differentials, settle plates (e.g. sessional and weekly), surface sampling (e.g. contact plates)

c. **Environmental parameters:** could include; air pressure differentials, temperature, air flow, microbiological monitoring

Unit 212 Prepare aseptic products

Level: **2**
Credit value: **10**

Unit aim
This unit introduces candidates to the legislation and policies around the preparation of aseptic products.
The aim of this unit is to provide the candidate with the skills needed for the preparation of aseptic for both dispensing and manufacturing.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Monitor the working environment
2. Prepare and maintain suitable working environments
3. Prepare a range of aseptic products
4. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
5. Operate within the limitations of the job role

Guided learning hours
It is recommended that **40** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards
This unit is linked to: 'Prepare aseptic products' Pharm 18.

Endorsement of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment and grading
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 212 Prepare aseptic products

Outcome 1 Monitor the working environment

Assessment Criteria

The learner can:

1. undertake relevant **environmental monitoring**
2. check that the parameters are within the set limits
3. take **appropriate action** if the **environmental parameters** (eg air pressure differentials are outside the set limits).

Range

a. **Environmental monitoring** could include; air sampling, settle plates (e.g. sessional and weekly), surface samples (e.g. contact plates, finger dabs)

b. **Appropriate action** could include; refer to colleague/supervisor, refer to manager

c. **Environmental parameters** could include; air pressure differentials, temperature, air flow, microbiological monitoring

Unit 212 Prepare aseptic products

Outcome 2 Prepare and maintain suitable working environments

Assessment Criteria

The learner can:

1. put on the appropriate clean room clothing following correct gowning procedure
2. clean and prepare the **environmental areas** using the correct materials
3. disinfect starting materials, **equipment/consumables** prior to introduction into and within the work area
4. clean and decontaminate all **work areas** using the correct cleaning method and removing all waste
5. store and dispose of waste materials in accordance with legal requirements.

Range

a. **Environmental areas**: could include; sterile preparation area, clean room, non-sterile preparation room, changing rooms
b. **Equipment/consumables:** could include; syringes, needles, filters, transfer devices, giving sets, venting device, raw materials
c. **Work areas:** could include; isolators, laminar flow cabinets

Unit 212 Prepare aseptic products

Outcome 3 Prepare a range of aseptic products

Assessment Criteria

The learner can:

1. prepare the **product** using the correct **process** and equipment according to worksheet and **Standard Operating Procedures (SOPs)**
2. label **product**, making all necessary accuracy **checks** and complete documentation in line with local policy.

Range

a. **Product:** could include; intravenous additives, parenteral nutrition, cytotoxic drugs, patient controlled analgesia (PCA) syringes, aseptic topical preparations (e.g. eye drops, irrigations), docking or reconstitution of dry powder vials, radiopharmaceuticals

b. **Processes:** could include; mixing, filtration, reconstitution, filling, transfer, dilution

c. **Standard operating procedures (SOPs)**: could include; basics of current legislation, current Good Manufacturing Practice, regulations and practice of industry, organisational, professional and ethical standards for preparing aseptic products

d. **Check:** could include; volume checks, visual product check, quality control sampling, reconciliation of labels, end of process check, equipment check.

Unit 212 Prepare aseptic products

Outcome 4 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. work within relevant **Standard Operating Procedures (SOPs)** including the relevant health and safety procedures and within own limits of responsibility
2. apply knowledge of **Standard Operating Procedures (SOPs)** within their job roles to the delivery of products and services.

Range

a. **Standard Operating Procedures (SOPs):** could include :basics of current legislation, current Good Manufacturing Practice, regulations and practice of industry, organisational, professional and ethical standards, local procedures for the preparation of aseptic products, including health and safety and control of substances hazardous to health (COSHH)

Unit 212 Prepare aseptic products

Outcome 5 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. take the corrective action within limits of own responsibility in the event of an **accident/incident/error** during the preparation
2. complete required **documentation** in this case
3. report to the appropriate person any problems outside the area of responsibility
4. feedback any near misses or errors to **appropriate person** to minimise future errors.

Range

a. **Accidents/incidents/error** could include; dropping equipment on the floor, puncturing a bag, using a wrong starting material, measuring an incorrect quantity, failure of equipment, the visual appearance of the product is not what was expected e.g. particles, colour, needle stick injuries, personal injury

b. **Documentation** could include; environmental monitoring records e.g. air pressure differential log, cleaning records, work sheets, equipment logs, quality exception reports, accident/incident forms, RIDDOR forms

c. **Appropriate person** could include; Pharmacist, Pharmacy technician, supervisor

Unit 213 Prepare documentation, materials, components and other items for the preparation of aseptic products

Level: 2
Credit value: 6

Unit aim
The aim of this unit is to provide the candidate with the skills needed to ensure that documentation, materials and other items are correctly prepared prior to the preparation of aseptic products.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Prepare, monitor and maintain suitable working environments
2. Complete documentation accurately
3. Prepare starting materials for the preparation of aseptic products
4. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
5. Operate within the limitations of the job role

Guided learning hours
It is recommended that **10** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards
This unit is linked to: 'Prepare documentation, materials, components and other items for the preparation of aseptic products' Pharm 21.

Endorsement of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment and grading
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 213 Prepare documentation, materials, components and other items for the preparation of aseptic products

Outcome 1 Prepare, monitor and maintain suitable working environments

Assessment Criteria

The learner can:

1. select and wear appropriate clothing
2. clean the appropriate **environmental areas** using the correct equipment and materials
3. keep the environmental work area clean and tidy
4. monitor relevant environmental parameters and ensure that where appropriate they are within set limits
5. apply knowledge of **sources of contamination** to ensure delivery of a quality product.

Range

a. **Environmental areas:** could include; laminar flow cabinet, clean room, isolators, non-sterile and sterile preparation room, changing rooms
b. **Sources of contamination:** could include**;** microbial, chemical, particulate

Unit 213 Prepare documentation, materials, components and other items for the preparation of aseptic products

Outcome 2 Complete documentation accurately

Assessment Criteria

The learner can:

1. generate worksheets according to local guidelines and protocols
2. select and confirm the correct worksheet for the **product**, completing any calculations as appropriate
3. allocate the batch number and expiry date for the product
4. make clear and accurate entries on all the relevant **documentation**.

Range

a. **Product:** could include; intravenous additives, parenteral nutrition, cytotoxic drugs, patient, controlled analgesia (PCA) syringes, aseptic topical preparations (e.g. eye drops, irrigations), docking or reconstitution of dry powder vials, radiopharmaceuticals

b. **Documentation:** could include; environmental monitoring records (e.g. air pressure differential log), cleaning records, work sheets, equipment logs, quality exception reports, batch worksheets, batch number allocation records

Unit 213 Prepare documentation, materials, components and other items for the preparation of aseptic products

Outcome 3 Prepare starting materials for the preparation of aseptic products

Assessment Criteria

The learner can:

1. generate complete, accurate and legible labels
2. ensure that all labels produced are accounted for
3. select the correct starting materials and **consumables**, for the product, recording the relevant information on the worksheet
4. confirm the starting materials and consumables are **fit for purpose**
5. disinfect the starting materials and consumables for transfer to the clean room.

Range

a. **Consumables:** could include; measures, mixers, pumps, filters, syringes, needles, transfer devices, venting devices, giving sets, alcohol wipes.

b. **Fit for purpose:** could include; intact packaging, clean non-contaminated packaging, within expiry date.

Unit 213 Prepare documentation, materials, components and other items for the preparation of aseptic products

Outcome 4 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. work within relevant **Standard Operating Procedures** including the relevant health and safety and COSHH procedures
2. work using the correct prescription or order.

Range

a. **Standard Operating Procedures (SOPs):** could include :basics of current legislation, current Good Manufacturing Practice regulations and practice of industry, organisational, professional and ethical standards, local procedures for the preparation prior to making aseptic products, including health and safety and control of substances hazardous to health (COSHH)

Unit 213 Prepare documentation, materials, components and other items for the preparation of aseptic products

Outcome 5 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. work within limits of own authority
2. report any problems outside own area of responsibility to an **appropriate person**
3. apply knowledge of industry, professional codes of practice and ethical standards within their job roles to the delivery of products and services.

Range

a. **Appropriate person:** could include; Pharmacist, Pharmacy technician, supervisor.

Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Level: 2
Credit value: 10

Unit aim

The aim of this unit is to provide the candidate with a basic understanding of health and safety procedures, including decontamination. The candidate will acquire the skills needed to assist in the preparation of documentation and material for the manufacture and assembly of medicinal products.

Learning outcomes

There are **five** learning outcomes to this unit. The learner will be able to:

1. Follow health and safety procedures in the work place
2. Assist in the preparation of the work area
3. Assist in the preparation and completion of the documentation and labels for the product
4. Select and prepare raw materials for the preparation of the product
5. Work within the limitations of the job role

Guided learning hours

It is recommended that **40** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national occupational standards

This unit is linked to: 'Assist in the preparation of documentation, materials, and other items for manufacture and assembly of medicinal products' Pharm 22.

Endorsement of the unit by a sector or other appropriate body

This unit is endorsed by Skills for Health.

Assessment and grading

This unit will be assessed by:

- Portfolio of evidence.

Guidance

The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.

Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.

The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Outcome 1 Follow health and safety procedures in the work place

Assessment Criteria

The learner can:

1. demonstrate an ability to work within **Standard Operating Procedures (SOPs)**
2. explain the importance of following health and safety procedures
3. demonstrate an understanding of COSHH procedures.

Range

b. **Standard Operating Procedures (SOPs):** could include ; basics of current legislation, current Good Manufacturing Practice regulations and practice of industry, organisational, professional and ethical standards, local procedures for the preparation prior to making or assembling medicinal products, including health and safety and control of substances hazardous to health (COSHH)

Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Outcome 2 Assist in the preparation of the work area

Assessment Criteria

The learner can:

1. ensure that appropriate clothing is worn at all times
2. identify different **sources of contamination**
3. deal with different sources of contamination appropriately
4. clean **environmental areas** using correct materials
5. monitor and record environmental parameters.

Range

a. **Sources of contamination:** could include; microbial, chemical, particulate cross contamination

b. **Environmental areas:** could include; laminar flow cabinets, clean room, isolators, non-sterile and sterile preparation room, changing rooms.

Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Outcome 3 Assist in the preparation and completion of the documentation and labels for the product

Assessment Criteria

The learner can:

1. confirm that they have the correct worksheet and labels for product
2. confirm the batch number and expiry date for **product**
3. make clear and accurate entries on **documentation**.

Range

a. **Product:** could include; topical fluids, IV preparations, solid dose forms (capsules, tablets, powders, suppositories), ointments and creams, oral mixtures, emergency boxes, pre-packed items and over labelling

b. **Documentation:** could include; Pre printed work sheets, batch records, batch work sheets, batch number allocation record, environmental maintaining records (e.g. air pressure reading records), cleaning records and equipment logs

Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Outcome 4 Select and prepare raw materials for the preparation of the product

Assessment Criteria

The learner can:

1. select correct materials, **consumables and equipment** in sufficient quantities to prepare the product
2. confirm materials are **fit for purpose**
3. ensure that first check is carried out by an **appropriate person**
4. prepare raw materials, **consumables and equipment** for transfer to work area
5. transfer materials to work area.

Range

a. **Consumables and equipment:** could include; balances, measures, mixers, pumps, filters, tablet counters, steriliser (e.g. autoclave, dry heat oven
b. **Appropriate person:** could include; pharmacist, pharmacy technician, supervisor
c. **Fit for Purpose:** could include; intact packaging, clean, non-contaminated packaging, within expiry date

Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products Unit 214 Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Outcome 5 Work within the limitations of the job role

Assessment Criteria

The learner can:

1. demonstrate how to work within limits of own responsibility
2. identify when to refer to an **appropriate person**.

Range

a. **Appropriate person**; could include: pharmacist, pharmacy technician, supervisor

Unit 314 Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Level: 3
Credit value: 4

Unit aim
This unit enables learners to have the skills to check their own dispensing work prior to the final accuracy check.

Learning outcomes
There are **six** learning outcomes to this unit. The learner will be able to:
1. Confirm the prescription is suitable for dispensing
2. Check dispensed items
3. Resolve dispensing errors and near misses
4. Confirm in-process accuracy check
5. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards
6. Operate within the limitations of the job role

Guided learning hours
It is recommended that **11** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards
This unit is linked to the Pharm 27.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence.

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.

Evidence must be provided across **all** the assessment criteria and must cover a variety of examples from the range, appropriate to the learners' practice.

The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

A clinical check is carried out by a prescriber and/or a pharmacist and ensures the prescription meets the appropriate legal, safety and clinical criteria.

A Final Accuracy Check is the accuracy checking process performed on dispensed items by a suitably qualified person immediately prior to the dispensed medicines/products being issued to individuals or their representatives and includes a check that nothing has changed since the last clinical check

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5, 6**

Unit 314 Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Outcome 1 Confirm the prescription is suitable for dispensing

Assessment Criteria

The learner can:

1. ensure that the prescription has been clinically screened and confirmed as suitable to dispense
2. check with the **appropriate person** to confirm that the prescription is valid.

Range

a. **Appropriate person**: could include; a pharmacist, prescriber or pharmacy technician

Unit 314 Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy checkUnit 314Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Outcome 2 Check dispensed items

Assessment Criteria

The learner can:

1. check the correct item has been selected and is **fit for purpose**
2. check the correct strength, form and quantity of **medicines** have been dispensed
3. check the label against the prescription and ensure the contents and directions match the **prescribed items**
4. check that the assembled items are **fit for purpose** and appropriately packaged
5. check that appropriate **devices and sundry items** are included
6. check future supply arrangements are made when sufficient stock is not available
7. annotate and endorse the prescription or documentation.

Range

a. **Fit for purpose**: could include; intact presentable packaging, clean, non-contaminated packaging, within expiry date for course of treatment, packaging complies with legal requirements and complies with relevant regulatory requirements

b. **Medicines and prescribed items**; could include; solid forms (tablets, capsules, pessaries, suppositories), liquid forms (oral, topical, injectable), preparations to be taken internally, preparations to be used externally, original packs, cytotoxic drugs, medical devices, appliances, controlled drugs

c. **Devices and sundry items**: could include; spoons, measuring cups, oral syringes and bungs, pharmacy bags, pill cutter and splitters or inhaler aids

Unit 314 Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Outcome 3 Resolve dispensing errors and near misses

Assessment Criteria

The learner can:

1. identify any **dispensing errors**
2. rectify dispensing errors
3. record dispensing errors
4. understand the causes and consequences of near misses and dispensing errors.

Range

a. **Dispensing errors**: could include; incorrect medicine, incorrect form, incorrect strength, incorrect quantity, incorrect labelling (medicine, form, strength, quantity directions, omitted cautionary information, storage, expiry date) incorrect container and closure, omitted patient information leaflet, measuring devices (dispensing cups, spoons, oral syringes and bungs) omitted warning cards (e.g. steroid, methotrexate), near miss (an error made during the dispensing process which is identified and rectified before the medicine has been finally checked and reaches the patient)

Unit 314 Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Outcome 4 Confirm in-process accuracy check

Assessment Criteria

The learner can:

1. pass the dispensed prescription on for a **final accuracy check** once the **in-process accuracy check** has been confirmed.

Range

a. **Final accuracy check**: includes a final check (process performed on dispensed items by a suitably qualified person immediate prior to the dispensed medicines/products being issued to individuals or their representatives and includes a check that nothing has changed since the last clinical check
b. **In-process accuracy check**: could include; second check of a prescription prior to the final accuracy check or a self check prior to passing on for a final accuracy check

Unit 314 Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Outcome 5 Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. demonstrate working in accordance with the **Standard Operating Procedures** at all times
2. demonstrate compliance with **legal, professional and organisational** requirements, guidelines and confidentiality at all times
3. apply knowledge of the types of medicines and supply
4. apply knowledge of common proprietary and generic names
5. apply knowledge of how medicines are administered
6. explain when and why patient medication records (PMRS) are used
7. explain the importance of maintaining **dispensary records**.

Range

a. **Standard operating procedures (SOPs)**: could include; protocols, regulations and practice of industry, organisational, professional and ethical standards, dispensing standards and procedures, checking dispensed items procedure, prescription endorsing procedures, near miss or dispensing error reporting

b. **Legal, professional and organisational**: could include; current pharmacy legislation, types of prescribers, professional and ethical standards that govern the dispensing of prescriptions, health and social legislation (data protection, confidentiality, equal opportunities), health and safety and control of substances hazardous to health

c. **Dispensary records**: could include; paper records or electronic records, unavailable stock

Unit 314 Undertake an in-process accuracy check of assembled prescribed items prior to the final accuracy check

Outcome 6 Operate within the limitations of the job role

Assessment Criteria

The learner can:

1. explain the limits of your own authority
2. report any problems to the **appropriate person**.

Range

a. **Appropriate person:** suitably qualified person, could be a pharmacist, prescriber or pharmacy technician.

Unit 216 Assist in the issuing of prescribed items

Level: **2**
Credit value: **3**

Unit aim
This unit will enable the learner to correctly issue prescribed items to individuals. The learner will work within current regulatory and ethical frameworks.

Learning outcomes
There are **five** learning outcomes to this unit. The learner will be able to:
1. Confirm the identity of the individual
2. Identify whether the individual is taking other medication
3. Issue prescribed items
4. Operate within the limitations of the job role at all times
5. Comply with current legislation, policy, good practice, organisational and professional codes of practice and ethical standards

Guided learning hours
It is recommended that **15** hours should be allocated for this unit, although patterns of delivery are likely to vary.

Details of the relationship between the unit and relevant national standards
This unit is linked to the Pharm 32.

Support of the unit by a sector or other appropriate body
This unit is endorsed by Skills for Health.

Assessment
This unit will be assessed by:
- Portfolio of evidence

Guidance
The learning outcomes in the following unit ask to provide evidence to show that the learner can consistently (over a period of time) work to all of the assessment criteria.
Evidence must be provided across **all** the assessment criteria and must cover a variety of example s from the range, appropriate to the learners' practice.
The activities must be the result of real work activities completed by learner and observed in the workplace as indicated in the centre requirements.

Simulation will not be accepted for these learning outcomes: **1, 2, 3, 4, 5**

Unit 216 Assist in the issuing of prescribed items

Outcome 1 Confirm the identity of the individual

Assessment Criteria

The learner can:

1. confirm the **individuals' identity** correctly matches the prescription
2. maintain the confidentiality of the individual at all times.

Range

a. **Individuals' identity**: could include; name, address, date of birth, NHS/hospital number

Unit 216 Assist in the issuing of prescribed items

Outcome 2 Identify whether the individual is taking other medication

Assessment Criteria

The learner can:

1. establish whether the individual has previously used this **medication or product**
2. establish whether the individual is taking other medication either prescribed or non-prescribed
3. refer the individual to an **appropriate person** if needed.

Range

a. **Medicine/product:** could include; tablets, capsules, external liquids, internal liquids, inhalers and devices, eye/ear preparations, nasal preparations, suppositories and enemas, pessaries and vaginal creams, dressings, topical preparations, patches, sublingual sprays/tablets

b. **Appropriate person:** could include; a pharmacist, pharmacy technician, healthcare professional.

Unit 216 Assist in the issuing of prescribed items

Outcome 3 Issue prescribed items

Assessment Criteria

The learner can:

1. confirm the **medicine or product** matches the prescription
2. correctly issue the **medicine or product**
3. provide all relevant devices/sundry items
4. apply knowledge of how to deal with individuals with special needs
5. provide **information** on storage and maintenance of prescribed items

Range

a. **Medicine/product:** could include; tablets, capsules, external liquids, internal liquids, inhalers and devices, eye/ear preparations, nasal preparations, suppositories and enemas, pessaries and vaginal creams, dressings, topical preparations, patches, sublingual sprays/tablets.

b. **Information:** could include; storage, repeat supply, expiry date, outstanding balance, dosage and usage, other medications in written, oral or electronic forms.

Unit 216 Assist in the issuing of prescribed items

Outcome 4 Operate within the limitations of the job role at all times

Assessment Criteria

The learner can:

1. confirm that issuing the prescribed items is within the limit of your responsibility
2. identify when the individual needs further advice or information
3. refer the individual to an **appropriate person** in a polite and courteous manner passing on all the relevant information.

Range

a. **Appropriate person:** could include; pharmacist, pharmacy technician, healthcare professional

Unit 216 Assist in the issuing of prescribed items

Outcome 5 Comply with current legislation, policy, good practice, organisational, and professional codes of practice and ethical standards

Assessment Criteria

The learner can:

1. demonstrate working in accordance with the **Standard Operating Procedures** at all time
2. complete all relevant records in accordance with **Standard Operating Procedures (SOPs)**
3. demonstrate compliance with legal, professional and organisational requirements, guidelines and confidentiality at all times
4. demonstrate a basic knowledge of the current **ethical and legal requirements** that govern the issuing of a prescription.

Range

a. **Standard operating procedures (SOPs):** could include; basics of current legislation, regulations and practice of industry, organisation, professional and ethical standards, local procedures for issuing prescribed items and dispensing records

b. **Ethical and legal requirements** could include; current pharmacy legislation, professional guidance, confidentiality, local procedures, health and social legislation e.g. data protection, confidentiality, equal opportunities that govern issuing of prescribed items

Appendix 1 Sources of general information

The following documents contain essential information for centres delivering City & Guilds qualifications. They should be referred to in conjunction with this handbook. To download the documents and to find other useful documents, go to the **Centres and Training Providers homepage** on **www.cityandguilds.com**.

Centre Manual - Supporting Customer Excellence contains detailed information about the processes which must be followed and requirements which must be met for a centre to achieve 'approved centre' status, or to offer a particular qualification, as well as updates and good practice exemplars for City & Guilds assessment and policy issues. Specifically, the document includes sections on:

- The centre and qualification approval process
- Assessment, internal quality assurance and examination roles at the centre
- Registration and certification of candidates
- Non-compliance
- Complaints and appeals
- Equal opportunities
- Data protection
- Management systems
- Maintaining records
- Assessment
- Internal quality assurance
- External quality assurance.

Our Quality Assurance Requirements encompasses all of the relevant requirements of key regulatory documents such as:

- Regulatory Arrangements for the Qualifications and Credit Framework (2008)
- SQA Awarding Body Criteria (2007)
- NVQ Code of Practice (2006)

and sets out the criteria that centres should adhere to pre and post centre and qualification approval.

Access to Assessment & Qualifications provides full details of the arrangements that may be made to facilitate access to assessments and qualifications for candidates who are eligible for adjustments in assessment.

The **centre homepage** section of the City & Guilds website also contains useful information such on such things as:

- **Walled Garden:** how to register and certificate candidates on line
- **Events**: dates and information on the latest Centre events
- **Online assessment**: how to register for e-assessments.

Centre Guide – Delivering International Qualifications contains detailed information about the processes which must be followed and requirements which must be met for a centre to achieve

'approved centre' status, or to offer a particular qualification. Specifically, the document includes sections on:

- The centre and qualification approval process and forms
- Assessment, verification and examination roles at the centre
- Registration and certification of candidates
- Non-compliance
- Complaints and appeals
- Equal opportunities
- Data protection
- Frequently asked questions.

Useful contacts

UK learners **General qualification information**	**T: +44 (0)844 543 0033** **E: learnersupport@cityandguilds.com**
International learners General qualification information	T: +44 (0)844 543 0033 F: +44 (0)20 7294 2413 E: **intcg@cityandguilds.com**
Centres Exam entries, Certificates, Registrations/enrolment, Invoices, Missing or late exam materials, Nominal roll reports, Results	T: +44 (0)844 543 0000 F: +44 (0)20 7294 2413 E: **centresupport@cityandguilds.com**
Single subject qualifications Exam entries, Results, Certification, Missing or late exam materials, Incorrect exam papers, Forms request (BB, results entry), Exam date and time change	T: +44 (0)844 543 0000 F: +44 (0)20 7294 2413 F: +44 (0)20 7294 2404 (BB forms) E: **singlesubjects@cityandguilds.com**
International awards Results, Entries, Enrolments, Invoices, Missing or late exam materials, Nominal roll reports	T: +44 (0)844 543 0000 F: +44 (0)20 7294 2413 E: **intops@cityandguilds.com**
Walled Garden Re-issue of password or username, Technical problems, Entries, Results, e-assessment, Navigation, User/menu option, Problems	T: +44 (0)844 543 0000 F: +44 (0)20 7294 2413 E: **walledgarden@cityandguilds.com**
Employer Employer solutions, Mapping, Accreditation, Development Skills, Consultancy	T: +44 (0)121 503 8993 E: **business@cityandguilds.com**
Publications Logbooks, Centre documents, Forms, Free literature	T: +44 (0)844 543 0000 F: +44 (0)20 7294 2413

If you have a complaint, or any suggestions for improvement about any of the services that we provide, email: feedbackandcomplaints@cityandguilds.com

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