Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Assurance of Regulatory and Good Practice Requirements in Pharmacy Technical Services

Unit Reference Number: J/652/4158

Level: Four (4)

Credit Value: 6

Minimum Guided Learning Hours: 36

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand requirements governing service quality	1.1 Interpret regulatory and organisational requirements relevant to quality assurance of a defined pharmacy technical service
	1.2 Identify the bodies, authorisations and sources of requirements relevant to a defined technical service
	1.3 Analyse the consequences of a breach of requirements for product quality, service users and the organisation
2. Understand assurance of applicable good practice controls	2.1 Explain the purpose of good practice controls relevant to the service setting
	2.2 Evaluate how documented controls support consistency and traceability in a defined activity
3. Be able to review evidence of compliance with applicable controls	3.1 Compare a defined service process and its records with applicable quality requirements
	3.2 Document compliance findings with reference to relevant requirements and evidence
	3.3 Review the currency and traceability of records used to support quality assurance or inspection
4. Be able to respond to compliance findings	4.1 Distinguish actual or potential non-compliance from acceptable variation in a defined case

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	4.2	Report compliance findings and recommend proportionate follow-up through approved quality routes
	4.3	Support a defined inspection or compliance review activity within delegated authority

Indicative Content	
LO1	AC 1.1 must include interpretation of the requirements that actually apply to the defined service and how they affect its quality assurance. These could include legislation, authorisation conditions, relevant good practice and organisational procedures. AC 1.2 must include identification of relevant oversight bodies, service authorisations and authoritative sources of requirements, distinguishing their respective roles. It could include explaining why approval of a service does not constitute approval of this qualification. AC 1.3 must include analysis of possible effects of a breach on quality, service users and the organisation, with consideration of seriousness and referral. It could include traceability, safety, supply or compliance consequences.
LO2	AC 2.1 must include the purpose of good practice controls applicable to the specified setting and the risks they address. Controls could be drawn from GMP, GDP or aseptic practice where those requirements apply. AC 2.2 must include evaluation of how documented controls in a defined activity support consistent performance and a traceable account of what occurred. It could include approved instructions, equipment status, checks and records.
LO3	AC 3.1 must include comparison of a defined process and its records with the applicable requirements, identifying conformity, exceptions and gaps in evidence. It could include examination of a control point or documented check. AC 3.2 must include factual findings linked to the relevant requirement and identifiable supporting evidence. It could include a source-record reference, document version, date and distinction between a confirmed finding and an unresolved question. AC 3.3 must include review of whether records are current, complete, attributable and retrievable for assurance or inspection, including recognition of missing or restricted evidence. It could include version and approval-status checks.
LO4	AC 4.1 must include comparison of the case with authorised limits or procedures and a reasoned distinction between acceptable variation and actual or potential non-compliance. It could include consideration of uncertainty or incomplete evidence. AC 4.2 must include reporting of findings and a proportionate follow-up recommendation through an approved route, recognising decisions outside delegated authority. It could include referral for investigation, containment or CAPA. AC 4.3 must include a defined contribution to an inspection or compliance

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	review within delegated authority, with accurate handling of evidence or requests and handover to the authorised lead. It could be evidenced through a realistic controlled review exercise.

Assessment Requirements
Applicable requirements depend on the activity, authorisations and local setting. GMP, GDP or other good practice regimes are considered only where relevant. Practical criteria concern review, monitoring and reporting of compliance evidence; they do not assess the learner performing medicines preparation, dispensing or supply. Inspection evidence may arise from a delegated support role or a realistic case. Participation in inspection preparation may use an approved controlled exercise where live access is unavailable; the learner is not the authorised regulatory signatory.

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