Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Audit and Assurance of Pharmacy Technical Service Processes

Unit Reference Number: R/652/4160

Level: Four (4)

Credit Value: 6

Minimum Guided Learning Hours: 36

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Be able to plan a defined quality systems or process audit	1.1 Define the scope, criteria and evidence sources for a quality systems or process audit
	1.2 Plan audit activities that account for independence, confidentiality and operational constraints
2. Be able to conduct and document audit activity	2.1 Gather and assess system or process evidence against the agreed audit criteria
	2.2 Record audit findings with a clear link to supporting evidence
	2.3 Communicate audit findings to relevant people through the approved reporting route
3. Be able to interpret audit findings and follow-up requirements	3.1 Analyse audit findings to identify recurring issues and potential quality risks
	3.2 Recommend proportionate follow-up based on the audit findings
	3.3 Monitor progress and closure evidence for agreed audit actions
4. Be able to support external inspection of quality systems	4.1 Explain the role of quality assurance records and delegated staff in supporting an external inspection
	4.2 Assess how an inspection finding should enter the local quality management process

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	4.3 Support preparation for or response to an external inspection within an agreed remit

Indicative Content	
LO1	AC 1.1 must include the audit objective, boundary, agreed criteria and suitable evidence sources for a defined system or process audit. It could include a risk-based sampling rationale. AC 1.2 must include arrangements for access, scheduling, impartiality, confidentiality and communication that make the planned audit practicable. It could include management of a conflict of interest or operational disruption.
LO2	AC 2.1 must include gathering and judging evidence against the agreed criteria, including its relevance and sufficiency. Methods could include record review, observation and appropriate questioning. AC 2.2 must include factual findings that identify the criterion assessed and the evidence supporting the conclusion. It could distinguish conformity, non-conformity, observation and matters that could not be verified. AC 2.3 must include communication through the approved reporting route of findings, supporting evidence and any required response, within the auditor's authority. It could include an auditee response or locally defined finding grade.
LO3	AC 3.1 must include analysis of patterns, significance and possible quality risks across audit findings, recognising limitations in the evidence. It could consider repeated findings, severity or affected controls. AC 3.2 must include a follow-up recommendation proportionate to the findings and risk, including the need for ownership and approval. It could propose a control change, corrective action or further investigation. AC 3.3 must include monitoring of agreed action progress and examination of completion evidence, with referral of overdue or inadequate responses. It could include an action tracker; formal closure remains with the authorised person where required.
LO4	AC 4.1 must include the purpose of quality assurance records and the responsibilities and authority limits of staff supporting an external inspection. It could include document retrieval and referral of specialist questions. AC 4.2 must include how an inspection finding is recorded, risk reviewed, assigned and followed up through the local quality system. It could involve a deviation or CAPA route. AC 4.3 must include a defined practical contribution to inspection preparation or response, using controlled evidence and accurate records within the agreed remit. It could be evidenced through a controlled inspection exercise.

Assessment Requirements
Audit criteria concern evidence of system, process or control compliance and do not assess the auditor's competence to perform the underlying pharmacy technical activity. A defined audit may be simulated where equivalent evidence is available. Supporting an external inspection does not imply acting as lead inspector or certifying professional

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practice. Inspection and audit evidence can be generated through a bounded controlled exercise if the learner performs the required audit actions; supporting a real external inspection is not compulsory.

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