Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Quality Governance and Assurance Systems in Pharmacy Technical Services

Unit Reference Number: H/652/4157

Level: Four (4)

Credit Value: 6

Minimum Guided Learning Hours: 36

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand quality governance arrangements in technical services	1.1 Explain how quality governance structures assign accountability for assurance and escalation in a pharmacy technical service
	1.2 Analyse how information from quality systems informs governance decisions
2. Be able to review the operation of a quality management system	2.1 Explain how core elements of a quality management system interact to control quality risks
	2.2 Evaluate the implications of a change to a controlled procedure for the quality management system
	2.3 Review the implementation of an approved quality system change within own remit
3. Be able to review the performance of quality controls	3.1 Select approved requirements and evidence to review how a defined quality control is operating
	3.2 Interpret assurance information to identify control gaps and recommend action within own responsibility
	3.3 Record the findings and agreed follow-up from a review of a quality control
4. Be able to escalate quality concerns	4.1 Assess the significance of an identified concern to determine the appropriate escalation route

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	4.2	Record a quality concern through the relevant governance route
	4.3	Review the status of an escalated quality concern within own responsibility

Indicative Content	
LO1	AC 1.1 must include the allocation of accountability for quality oversight, operation of controls, assurance review and escalation in a defined pharmacy technical service. It could include responsibilities of service managers, quality teams and operational staff. AC 1.2 must include how information from more than one quality-system source is considered in a governance decision, including its significance and limitations. Sources could include deviations, audit findings, performance measures and overdue actions.
LO2	AC 2.1 must include how controlled procedures, training, records, change control, deviation handling, CAPA and review work together to manage quality risk. It could include an example of how a weakness in one element affects another. AC 2.2 must include the implications of a defined procedural change for responsibilities, related documents, records, training and control of implementation. It could include changes to a form, electronic workflow or monitoring arrangement. AC 2.3 must include a review of evidence that an approved change has been implemented within the learner's remit, identification of gaps and referral of concerns. Evidence could include current document versions, training records and revised forms.
LO3	AC 3.1 must include selection of the approved requirement and relevant evidence for reviewing a defined control, with a reason for the selection and recognition of evidence limitations. It could include a risk-based sample of records or indicators. AC 3.2 must include interpretation of evidence against the approved control, identification of any gap and a recommendation within the learner's responsibility. It could include an exception, adverse trend or incomplete check. AC 3.3 must include a traceable record of the control reviewed, evidence considered, findings and agreed follow-up. It could include an action owner, review date and reference to the approved reporting system.
LO4	AC 4.1 must include judgement of the potential impact, urgency and applicable escalation threshold for a defined concern. It could include consideration of patient or product impact, continuing exposure and uncertainty. AC 4.2 must include timely, factual communication and recording through the relevant governance route, including the concern, supporting information and any action already taken. It could include a quality-system entry and notification to a designated lead. AC 4.3 must include review of acknowledgement, ownership, progress and remaining risk within the learner's responsibility, with further referral where

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	needed. It could include checking an overdue action or an unresolved response.

Assessment Requirements

Practical evidence should relate to the learner's delegated quality assurance role and the quality system used in their setting. Monitoring concerns the operation of controls and procedures; it does not assess competence to perform pharmacy technical tasks. Escalation does not require decisions reserved for an authorised person.

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