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Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Quality Oversight of Aseptic Processes in Pharmacy Technical Services

Unit Reference Number: F/652/4165

Level: Four (4)

Credit Value: 8

Minimum Guided Learning Hours: 48

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Be able to review assurance evidence for specialist technical controls	1.1 Analyse how defined quality controls provide assurance at critical stages of aseptic preparation or another pharmacy technical service process
	1.2 Evaluate the possible quality implications of a defined control failure and the need for authorised review
	1.3 Review documented evidence that defined critical controls operated as specified
2. Be able to interpret assurance monitoring information	2.1 Compare authorised environmental or process monitoring results with approved parameters
	2.2 Assess the quality significance of variation and identify the appropriate reporting or escalation route
	2.3 Record and report an environmental or process monitoring concern through an approved quality route
3. Understand assurance evidence for validation and qualification	3.1 Explain the purpose of qualification and validation in a defined pharmacy technical service process
	3.2 Review the completeness and status of validation or qualification evidence to identify gaps requiring specialist follow-up
	3.3 Contribute to the collation of qualification or validation assurance evidence

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4.	Be able to escalate and review quality control failures	4.1 Assess evidence of a quality control failure and identify the need for containment, investigation and authorised product decisions
		4.2 Recommend quality system actions to reduce recurrence based on investigation findings
		4.3 Contribute factual control evidence to a defined quality failure investigation

Indicative Content	
LO1	AC 1.1 must including analysis of how controls at critical stages provide assurance against relevant quality risks in a defined process. It could consider premises, personnel, materials, equipment and checks associated with contamination or mix-up prevention. AC 1.2 must include evaluation of the possible implications of a defined control failure, including exposure, detectability, traceability and uncertainty, and why authorised review is needed. It could involve a premises, equipment or process concern. AC 1.3 must include review of documented evidence that specified critical controls operated as approved, identifying gaps or deviations and the limits of the conclusion. It could include monitoring or equipment-status records.
LO2	AC 2.1 must include comparison of defined monitoring results and relevant trends with approved parameters, taking account of the conditions under which results were obtained. It could include sampling context or equipment state. AC 2.2 must include judgement of the significance of variation and the appropriate reporting or escalation route. It could consider drift, an excursion, uncertainty, and alert or action limits where used. AC 2.3 must include a factual record and timely report of the result or trend, source, timing and possible affected process through an approved quality route. It could involve an excursion report; product disposition remains an authorised decision.
LO3	AC 3.1 must include the purpose of qualification and validation in showing that specified premises, equipment or processes are suitable and remain controlled. It could refer to approved protocols and ongoing monitoring. AC 3.2 must include review of the completeness and status of defined qualification or validation evidence, identifying matters requiring specialist follow-up. It could include protocols, results, deviations and approval status. AC 3.3 must include a contribution to collating traceable assurance evidence and identifying outstanding items for specialist review. It could include an evidence index, approved protocol version and deviation list.
LO4	AC 4.1 must include assessment of evidence about a defined control failure, the possible scope of its impact and the need for containment, investigation and authorised product decisions. It could involve monitoring, equipment or process records.

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	AC 4.2 must include quality-system actions linked to investigation findings and an explanation of how they could reduce recurrence. It could include CAPA, monitoring or controlled procedural change. AC 4.3 must include factual contribution of relevant control evidence to an investigation within delegated authority. It could include chronology, monitoring data and procedural checks; it does not include product release or clinical decisions.

Assessment Requirements
This is a specialist quality oversight unit. It assesses interpretation of control records, monitoring data and deviations, not competence to prepare medicines aseptically, supervise production, validate a process, approve environmental results or release products. Evidence may use authenticated data or scenarios where access is restricted. Decisions about product status remain with authorised personnel. Collating validation or qualification evidence and reviewing aseptic controls does not constitute validation approval, aseptic preparation or release of products.

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