Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Audit, Supplier Qualification and Inspection Readiness

Unit Reference Number: T/652/4199

Level: Five (5)

Credit Value: 5

Minimum Guided Learning Hours: 35

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand audit principles, processes and regulatory expectations within pharmaceutical environments	1.1 Evaluate the purpose, scope and application of different audit types within pharmaceutical quality management
	1.2 Evaluate the stages of the audit lifecycle and the responsibilities of those involved
	1.3 Assess regulatory expectations for pharmaceutical audit programmes and their contribution to continuous improvement
2. Be able to evaluate supplier qualification and ongoing supplier performance	2.1 Assess supplier risks to determine appropriate qualification and oversight requirements
	2.2 Evaluate supplier documentation to determine compliance with specified quality and regulatory requirements
	2.3 Analyse supplier audit and performance information to identify quality risks and compliance concerns
	2.4 Develop justified recommendations for supplier qualification, monitoring or improvement
3. Be able to prepare for and contribute to regulatory inspections	3.1 Assess regulatory inspection requirements and their implications for inspection preparation
	3.2 Prepare documentation and supporting evidence for a regulatory inspection

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		3.3	Communicate information clearly and professionally during an inspection or simulated inspection
		3.4	Evaluate inspection readiness arrangements and identify areas requiring improvement
4.	Be able to analyse audit and inspection findings and develop appropriate corrective actions	4.1	Evaluate audit and inspection findings to determine their significance and potential impact
		4.2	Apply structured investigation methods to identify potential causes of audit and inspection findings
		4.3	Develop corrective and preventive actions to address identified audit and inspection findings
		4.4	Evaluate CAPA effectiveness and recommend improvements to relevant quality management processes

Indicative Content	
LO1	1.1 must include the purpose and principles of auditing; internal and external audits; supplier audits; regulatory inspections; differences in objectives, scope, independence and outcomes; contribution to product quality and regulatory compliance. 1.2 must include audit planning, preparation, conduct, evidence gathering, reporting and follow-up; roles and responsibilities of auditors, auditees and relevant quality personnel; professional conduct, objectivity and effective communication. 1.3 must include relevant GMP requirements; expectations for self-inspection and supplier oversight; risk-based audit planning; documentation and follow-up requirements; use of audit outcomes to identify compliance weaknesses and support QMS improvement. Other examples include MHRA, EU GMP and FDA expectations where relevant to the operational context.
LO2	2.1 must include the purpose and lifecycle of supplier qualification; identification and evaluation of risks associated with materials, products and services; supplier criticality; risk-based selection of qualification and monitoring arrangements. Other examples include suppliers of starting materials, sterile components, consumables, equipment and contracted services. 2.2 must include review of relevant supplier documentation; identification of missing, incomplete or inadequate evidence; assessment against qualification requirements and quality expectations. Other examples include quality agreements, technical contracts, certificates of analysis, certificates of conformity and supplier audit reports. 2.3 must include interpretation of supplier audit findings and performance data; assessment of recurring quality concerns, deviations and compliance

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	weaknesses; implications for product quality, supply reliability and regulatory compliance. Other examples include delivery performance, rejected materials, complaints, deviations and repeat audit observations. 2.4 must include recommendations informed by supplier risk, documentation and performance evidence; appropriate qualification or monitoring actions; identification of further evidence or corrective actions required; justification of recommendations against quality and regulatory requirements.
LO3	3.1 must include the purpose, scope and structure of relevant regulatory inspections; expectations of inspectors and inspected organisations; inspection conduct; evidence and documentation requirements; responsibilities of personnel supporting an inspection. Other examples include MHRA inspections and FDA inspection arrangements where relevant. 3.2 must include identification, retrieval and organisation of relevant documentation; verification of completeness, accuracy and traceability; document-control requirements; preparation of appropriate evidence for inspection review. Other examples include procedures, training records, equipment qualification records, deviation reports, CAPA records and environmental monitoring information. 3.3 must include appropriate inspection behaviours; accurate and factual responses to questions; reference to supporting evidence; recognition of professional responsibilities and limitations; appropriate escalation of questions or concerns. 3.4 must include review of inspection preparation arrangements; assessment of documentation availability, staff preparedness and relevant quality-system controls; identification of compliance gaps; development of justified recommendations to strengthen inspection readiness.
LO4	4.1 must include interpretation of audit and inspection observations; relevant classification systems; assessment of compliance risks and potential implications for product quality and patient safety; determination of appropriate investigation and escalation requirements. Other examples include critical, major and minor observations and relevant regulatory inspection findings. 4.2 must include analysis of available audit and quality evidence; identification of contributory factors and potential root causes; consideration of procedural, organisational, equipment and human factors. Other examples include 5 Whys, Ishikawa diagrams and other appropriate root-cause analysis methods. 4.3 must include development of proportionate corrective and preventive actions; relationship between investigation findings and proposed measures; responsibilities, timescales and implementation considerations; appropriate documentation and follow-up requirements. 4.4 must include effectiveness criteria; evaluation of follow-up evidence; identification of recurring findings or unresolved risks; integration of audit outcomes and lessons learned into quality management and continuous improvement processes.

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Assessment Requirements

Assessment must demonstrate the application of specialist auditing, supplier qualification and regulatory inspection knowledge and skills within pharmaceutical manufacturing, aseptic services or pharmacy technical services environments.

Learners must demonstrate Level 5 analytical and evaluative capability, including the ability to interpret audit evidence, assess supplier risks, evaluate compliance findings and develop justified recommendations.

LO2, LO3 and LO4 require evidence of applied skills. Learners must undertake supplier evaluation activities, prepare inspection evidence, demonstrate professional communication and apply investigation and corrective action methods.

Assessment may use authentic workplace evidence or realistic technical scenarios supported by supplier records, audit reports, quality documentation and regulatory inspection information.

Learners are not required to act as lead auditors, independently approve suppliers, manage regulatory inspections or authorise CAPA.

The qualification does not confer occupational competence or professional authorisation in its own right.

Evidence may include:

- Evaluations of audit programmes and regulatory requirements
- Supplier qualification risk assessments
- Supplier documentation reviews
- Supplier performance evaluations
- Supplier qualification or improvement recommendations
- Audit plans and evidence reviews
- Inspection-readiness assessments
- Prepared inspection evidence packs
- Observed or simulated inspection discussions
- Audit and inspection findings analyses
- Root-cause investigation reports
- CAPA plans and effectiveness evaluations
- Professional discussions supported by technical evidence
- Authenticated workplace quality and supplier management records

LO1 – Audit principles and regulatory expectations

Learners should evaluate different types of audit and their roles within pharmaceutical quality management.

Assessment should require consideration of audit objectives, planning, conduct, reporting and follow-up, including how findings contribute to compliance and continuous improvement.

Learners should distinguish regulatory inspections from internal and supplier audits, recognising differences in authority, purpose and potential consequences.

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LO2 – Supplier qualification and oversight

Learners must undertake a realistic supplier evaluation.

The assessment should provide sufficient information to evaluate supplier risks, review relevant documentation and assess quality or performance concerns.

Learners should produce justified recommendations concerning supplier qualification, ongoing monitoring or improvement.

Assessment does not require learners to approve a supplier or conduct a complete supplier audit independently.

Where learners have appropriate workplace opportunities, participation in supplier audits or performance reviews may contribute evidence.

LO3 – Inspection readiness

Learners must prepare documentation and supporting evidence for a realistic regulatory inspection scenario.

Assessment should require them to identify relevant documentation, check its suitability and demonstrate appropriate inspection communication.

For AC 3.3, direct observation of communication is required. This may take place through participation in an authentic inspection-related activity or a suitably structured simulation.

A written explanation of appropriate inspection behaviour alone is not sufficient.

For AC 3.4, learners should evaluate the effectiveness of inspection preparation arrangements and develop justified recommendations.

LO4 – Audit findings and CAPA

Learners must analyse realistic audit or inspection findings and determine their significance.

Assessment should require application of an appropriate investigation methodology, identification of potential causes and development of justified corrective and preventive actions.

Learners must evaluate CAPA effectiveness using suitable follow-up evidence. This may be drawn from workplace records or a realistic case study.

Implementation of CAPA is not mandatory where this falls outside the learner's professional responsibilities.

An integrated assessment involving a supplier quality concern, subsequent audit findings and corrective action planning could provide evidence across several learning outcomes.

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