Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Quality Management Systems, Deviations and CAPA

Unit Reference Number: A/652/4190

Level: Five (5)

Credit Value: 6

Minimum Guided Learning Hours: 40

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand the structure, operation and effectiveness of pharmaceutical quality management systems	1.1 Evaluate the purpose, scope and regulatory expectations of pharmaceutical quality management systems
	1.2 Evaluate the functions and interrelationships of key pharmaceutical quality management processes
	1.3 Evaluate how quality risk management and continuous improvement are integrated within a pharmaceutical quality management system
	1.4 Analyse the impact of quality management system weaknesses on product quality and regulatory compliance
2. Be able to investigate pharmaceutical quality deviations and determine appropriate responses	2.1 Assess pharmaceutical quality deviations to determine their significance and investigation requirements
	2.2 Apply structured investigation methods to identify contributory factors and potential root causes of quality deviations
	2.3 Produce a compliant deviation investigation report containing evidence-based findings and conclusions
	2.4 Develop justified recommendations for the resolution and escalation of pharmaceutical quality deviations
3. Be able to develop and evaluate corrective and preventive actions within a	3.1 Develop corrective and preventive actions to address identified causes of pharmaceutical quality issues

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	3.2	Develop a CAPA plan incorporating appropriate responsibilities, timescales and effectiveness measures
	3.3	Evaluate the effectiveness of corrective and preventive actions using relevant quality evidence
	3.4	Evaluate the contribution of cross-functional working and CAPA outcomes to quality risk management and continuous improvement
4. Be able to apply change control processes to maintain pharmaceutical quality and regulatory compliance	4.1	Evaluate the requirements and potential implications of proposed changes within pharmaceutical operations
	4.2	Apply risk-based assessment methods to determine the potential impact of a proposed change
	4.3	Produce change control documentation incorporating justification, impact assessment and implementation requirements
	4.4	Evaluate the effectiveness of an implemented change and its impact on the validated and compliant state
	4.5	Develop recommendations to address issues identified through change control effectiveness reviews

Indicative Content	
LO1	1.1 must include the purpose and principles of a pharmaceutical quality management system; relevant GMP requirements; ICH Q10 principles; quality governance, regulatory compliance, product quality and patient safety. 1.2 must include standard operating procedures, document control, training and competence, deviation management, CAPA, change control and quality oversight; relationships between these processes and their contribution to a functioning QMS. 1.3 must include integration of QRM within QMS processes; ICH Q9 principles; risk-based decision-making; quality performance monitoring; management review and continuous improvement. 1.4 must include identification of quality-system weaknesses; inadequate procedures, training, documentation, oversight or escalation; relationship between systemic failures, recurring deviations, product quality risks and regulatory findings. Other examples include audit findings, repeated CAPA failures and recurring documentation errors.
LO2	2.1 must include deviation types and triggers; classification according to risk

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	and significance; potential implications for product quality, patient safety and regulatory compliance; investigation scope and escalation requirements. Other examples include minor, major and critical deviations, using the classification arrangements relevant to the quality system. 2.2 must include the deviation investigation process; collection and analysis of evidence; identification of contributory factors and potential root causes; distinction between immediate causes, human factors and systemic weaknesses. Other examples include 5 Whys, Ishikawa diagrams, FMEA and other suitable investigation tools. 2.3 must include investigation scope; description and classification of the deviation; evidence reviewed; investigation methodology; assessment of potential product and process impacts; justified conclusions; relevant documentation and data-integrity requirements. 2.4 must include evaluation of investigation findings; proportionate responses to identified risks; recommendations for containment, correction, escalation or further investigation; consideration of product quality, patient safety and relevant quality-system requirements.
LO3	3.1 must include the CAPA lifecycle; distinction between correction, corrective action and preventive action; development of actions linked to investigation findings; prevention of recurrence; consideration of implementation requirements. 3.2 must include CAPA objectives; risk-based prioritisation; defined actions; responsibilities and timescales; documentation and approval requirements; measurable effectiveness criteria. 3.3 must include CAPA effectiveness checks; evaluation of follow-up evidence against defined acceptance criteria; assessment of recurrence, residual risks and unintended consequences; identification of further actions where CAPA has not been effective. Other examples include repeat deviation trends, audit findings, quality metrics and follow-up monitoring results. 3.4 must include responsibilities of relevant quality and operational functions; coordination of CAPA activities; communication of findings; integration of lessons learned into QRM, procedures, training and continuous improvement processes.
LO4	4.1 must include the purpose and lifecycle of change control; identification and classification of proposed changes; assessment of their potential impact on product quality, patient safety, regulatory compliance and the validated state. Other examples include changes to documents, equipment, processes, facilities, materials and suppliers. 4.2 must include identification of affected processes, products and systems; assessment of risks and existing controls; consideration of qualification, validation, requalification and regulatory requirements; justification of proposed risk controls. 4.3 must include description and justification of the proposed change; documented impact and risk assessments; required actions and responsibilities; implementation arrangements; verification or validation requirements; relevant review and approval stages. 4.4 must include post-implementation review; comparison of outcomes against

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	change objectives and acceptance criteria; evaluation of residual risks and unintended consequences; consideration of ongoing compliance and the maintenance of the validated state. 4.5 must include interpretation of post-implementation findings; identification of outstanding risks or compliance gaps; justified recommendations for further controls, corrective actions or additional qualification or validation activities.

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Assessment Requirements

Assessment must demonstrate the application of specialist quality management 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 quality evidence, investigate deviations, identify systemic weaknesses, develop CAPA and assess the impact of proposed or implemented changes.

LO2, LO3 and LO4 require evidence of applied skills. Learners must demonstrate the ability to undertake structured investigations, produce relevant quality documentation, develop appropriate actions and evaluate their effectiveness.

Assessment may use authentic workplace evidence or realistic technical scenarios supported by suitable quality records, investigation evidence, CAPA information and change control documentation.

Learners are not required to hold formal quality management authority, independently approve deviations or CAPA, authorise changes or make final product-release decisions.

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

Evidence may include:

- Evaluations of pharmaceutical quality management arrangements
- Reviews of QMS processes and quality performance data
- Deviation assessments and investigation reports
- Root-cause analysis records
- CAPA plans and effectiveness evaluations
- Quality risk assessments
- Completed change control documentation
- Change impact assessments
- Post-implementation reviews
- Workplace improvement projects
- Professional discussions supported by relevant technical evidence

LO1 – Quality management systems

Assessment should require learners to evaluate how the different elements of a pharmaceutical QMS operate together.

Learners should consider the effectiveness of quality-system arrangements, including how weaknesses in procedures, training, documentation or oversight may contribute to recurring quality problems.

Assessment should go beyond describing the components of a QMS.

LO2 – Deviation investigations

Learners must investigate a realistic pharmaceutical quality deviation.

The evidence should be sufficiently detailed to enable learners to assess the deviation's

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significance, select and apply an appropriate investigation methodology, consider multiple potential causes and produce justified conclusions.

The investigation report must be completed by the learner, although an authentic workplace report may be used where their contribution is identifiable.

A definitive root cause is not essential where the available evidence does not support one. Learners should recognise uncertainty and identify any further investigation needed.

LO3 – Corrective and preventive action

Learners must develop a CAPA plan linked to identified quality issues and investigation findings.

The plan should establish appropriate actions, responsibilities, timescales and measurable effectiveness criteria.

For AC 3.3, learners must evaluate effectiveness using relevant post-implementation evidence. Where workplace CAPA implementation is outside their responsibilities, suitable case-study evidence may be used.

Actual implementation of CAPA is not mandatory.

LO4 – Change control

Learners must apply change control principles to a realistic pharmaceutical change.

Assessment should require an evaluation of the proposed change, a documented risk and impact assessment, and preparation of appropriate change control documentation.

Learners must also evaluate post-implementation evidence to determine whether the change has achieved its objectives and whether the validated and compliant state has been maintained.

Actual authorisation or implementation of a change is not required.

An integrated assessment could use a single quality problem that results in a deviation investigation, CAPA and subsequent change control. However, the evidence must clearly demonstrate each relevant AC.

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