Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Quality Deviation Investigation and Corrective and Preventive Action

Unit Reference Number: T/652/4161

Level: Five (5)

Credit Value: 8

Minimum Guided Learning Hours: 48

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Be able to scope and investigate a quality deviation	1.1 Assess the potential quality impact of a complex deviation and recommend containment and escalation within delegated authority
	1.2 Plan and coordinate an investigation using appropriate information sources.
	1.3 Document the scope, evidence sources and provisional findings of the investigation
2. Be able to analyse causes and limitations of evidence	2.1 Apply and adapt root cause methods to test plausible causes of the deviation
	2.2 Evaluate competing explanations and the strength of the available evidence
	2.3 Document justified causal conclusions and limitations of the evidence
3. Be able to develop and support implementation of corrective and preventive action	3.1 Design a proportionate CAPA proposal that addresses supported causes and residual quality risks
	3.2 Justify the proposed actions against alternative responses and operational constraints
	3.3 Coordinate implementation of a defined approved corrective or preventive action within delegated authority
4. Be able to evaluate and revise Corrective and Preventative Action (CAPA)	4.1 Define measures and review points for assessing CAPA implementation and effectiveness

The intellectual property rights remain with Open Awards.

	4.2	Evaluate effectiveness findings and recommend revision or escalation where risk remains
	4.3	Analyse deviation or action trends to identify recurring quality-system weaknesses

Indicative Content	
LO1	AC 1.1 must include reasoned assessment of a complex deviation's possible scope, impact and uncertainty, with containment and escalation recommended within delegated authority. It could consider affected processes, records or products; product disposition remains an authorised decision. AC 1.2 must include a coordinated investigation plan covering scope, priorities, information sources, relevant people and responsibilities. It could include records, interviews, chronology and dependencies between investigation activities. AC 1.3 must include a controlled record of investigation scope, source evidence, provisional findings, gaps and relevant referrals. It could include a chronology, evidence index and versioned updates.
LO2	AC 2.1 must include application and adaptation of a suitable causal method to test plausible causes against evidence, distinguishing symptoms from underlying factors. Methods could include causal mapping, 5 Whys or a fishbone diagram. AC 2.2 must include reasoned comparison of competing explanations and the strength, consistency and limitations of supporting evidence. It could consider conflicting records, missing data or bias. AC 2.3 must include documented causal conclusions linked to evidence, consideration of alternatives and explicit limits to confidence. It could separate a supported cause from a contributing factor or untested assumption.
LO3	AC 3.1 must include a proportionate CAPA proposal linked to supported causes and residual risk, covering intended effect, ownership, implementation and approval needs. It could include immediate correction alongside longer-term preventive control. AC 3.2 must include justification of the proposed actions against credible alternatives using risk reduction, feasibility and operational constraints. It could include resource needs, unintended effects and authorisation requirements. AC 3.3 must include coordination of implementation of a defined approved action within delegated authority, with a record of contribution and barriers. It could include controlled changes, assigned tasks and progress checks; clinical and product decisions remain with authorised personnel.
LO4	AC 4.1 must include measures and review points that distinguish whether CAPA was implemented from whether it reduced the underlying risk. It could include a baseline, recurrence indicator, sampling period or process measure. AC 4.2 must include evaluation of effectiveness evidence, residual risk and any justified need for revision or escalation. It could include recurrence, incomplete data or an unintended effect.

The intellectual property rights remain with Open Awards.

	AC 4.3 must include analysis of deviation or action data to identify and explain a recurring quality-system weakness, with a justified recommendation. It could include repeated causes, severity or delayed actions.

Assessment Requirements

This Level 5 unit assumes the learner can coordinate a defined quality investigation and design a CAPA proposal within delegated authority. Clinical assessment, product disposition, regulatory reporting and formal closure approvals remain with authorised personnel. Evidence should show reasoned choices, alternatives and effectiveness checks; an authentic complex case may supplement restricted workplace access. The learner must show a contribution to an approved action and documented follow-up, but formal approval and closure remain with authorised personnel.

The intellectual property rights remain with Open Awards.