Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Assurance of Quality Documentation and Data Integrity

Unit Reference Number: Y/652/4162

Level: Four (4)

Credit Value: 5

Minimum Guided Learning Hours: 30

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand documentation and data integrity requirements	1.1 Explain how documentation and data integrity principles protect product and service quality
	1.2 Analyse risks to integrity across the life cycle of quality information
2. Be able to review controlled quality records	2.1 Select current quality assurance records and document review findings in accordance with defined procedures
	2.2 Review relevant records for completeness, consistency and traceability against quality requirements
	2.3 Complete or update an authorised quality assurance record in accordance with document controls
3. Be able to identify and address data integrity concerns	3.1 Assess a potential documentation or data integrity concern using relevant evidence
	3.2 Report and document the concern through the appropriate organisational route
4. Understand improvements to information control	4.1 Evaluate a defined weakness in document or record control
	4.2 Recommend a change that improves reliability without undermining traceability
	4.3 Explain how confidentiality and data-protection requirements govern access to and sharing of quality records

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Indicative Content	
LO1	AC 1.1 must include how documentation and data integrity principles make quality information reliable, traceable and available for review. It could use ALCOA+ to explain attribution, timely recording, accuracy and completeness. AC 1.2 must include risks to quality information from creation through amendment, access, storage, retrieval and retention, across relevant record formats. It could include uncontrolled copies, missing audit trails or inappropriate access.
LO2	AC 2.1 must include selection of current authorised quality assurance records and documentation of review findings under the defined procedure. It could use audit, document-review or deviation-support records rather than operator production records. AC 2.2 must include checks of completeness, consistency and traceability against the relevant quality requirements, with discrepancies identified. It could include attribution, dates, cross-references and comparison with source records. AC 2.3 must include completion or updating of an authorised quality assurance record using the correct controls for version, attribution, amendments and review. It could be an audit or deviation-support record; operator production, dispensing and clinical records are outside the assessed activity.
LO3	AC 3.1 must include assessment of a defined documentation or data integrity concern using available evidence and recognition of what remains uncertain. It could involve unexplained amendments, conflicting entries or incomplete audit trails. AC 3.2 must include factual reporting through the appropriate route, preservation of original evidence and action within authority and confidentiality requirements. It could include an integrity concern entered into an approved quality system.
LO4	AC 4.1 must include evaluation of a defined control weakness and its effect on the reliability or availability of quality information. It could involve version distribution, permissions, retention or retrieval. AC 4.2 must include a proportionate proposed change that addresses the weakness while retaining traceability and appropriate approval. It could include a controlled check, access change or review prompt. AC 4.3 must include how confidentiality and data-protection requirements govern access, sharing and retention of quality records, while preserving source evidence. It could include redaction or secure disclosure for audit or assessment.

Assessment Requirements
Assessment concerns quality assurance records, document control and review of source records where authorised. The unit does not assess the learner completing batch, dispensing or clinical records as an operator. Electronic or paper evidence may be used, with appropriate access, confidentiality and preservation of the original record. A learner may complete quality assurance records they are authorised to maintain; production, dispensing, clinical and product-release records are not assessed as

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