Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Scientific and Technical Reporting for Regulated Settings

Unit Reference Number: H/652/4200

Level: Five (5)

Credit Value: 5

Minimum Guided Learning Hours: 30

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand scientific and technical writing principles and regulatory documentation requirements	1.1 1.1 Evaluate the principles of effective scientific and technical writing within regulated environments
	1.2 1.2 Evaluate regulatory and data-integrity requirements applicable to scientific and technical documentation
	1.3 1.3 Assess the contribution of effective technical documentation to product quality, regulatory compliance and decision-making
2. Be able to produce and evaluate standard operating procedures and controlled documents	2.1 Produce a standard operating procedure using appropriate structure, terminology and document-control requirements
	2.2 Apply traceability and data-integrity principles when producing controlled documentation
	2.3 Evaluate the clarity, accuracy and usability of a standard operating procedure
	2.4 Apply document review and change control requirements to the revision of a controlled document
3. Be able to produce scientific and technical reports for regulated pharmaceutical environments	3.1 Produce a scientific or technical report using appropriate structure and regulatory documentation principles
	3.2 Present scientific and technical data using appropriate formats and visual representations

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		3.3	Interpret technical findings and develop evidence-based conclusions and recommendations
		3.4	Adapt scientific and technical reports to meet the information needs of different audiences
4.	Be able to communicate scientific and technical information effectively to stakeholders	4.1	Select and apply appropriate communication approaches for different technical and non-technical stakeholders
		4.2	Present technical findings and recommendations clearly and accurately to relevant stakeholders
		4.3	Communicate sensitive or complex technical information professionally to support informed decision-making
		4.4	Evaluate the effectiveness of technical communication and recommend improvements

Indicative Content	
LO1	1.1 must include clarity, accuracy, conciseness, objectivity and appropriate structure; use of technical terminology; presentation of complex information; consistency and suitability for the intended purpose and audience. 1.2 must include relevant GMP documentation requirements; ALCOA+ principles; document control, traceability, version control and record retention; requirements for accurate, complete and reliable information; the document lifecycle. 1.3 must include the role of documentation in establishing evidence, supporting traceability and demonstrating compliance; implications of incomplete, inaccurate or unclear documentation for product quality, patient safety and regulatory decisions.
LO2	2.1 must include the purpose and structure of SOPs; appropriate document templates; scope, responsibilities, procedural steps and associated records; clear and consistent language; relevant document-control information. 2.2 must include clear identification of requirements and supporting information; accurate references; appropriate document identifiers and version information; consistency between procedures and associated records; application of relevant data-integrity requirements. 2.3 must include assessment of technical accuracy, completeness, clarity and sequence; suitability for intended users; identification of ambiguities or potential errors; recommendations for improving procedural effectiveness. 2.4 must include identification and justification of required amendments; document review procedures; recording and traceability of changes; version control; consideration of approval, implementation and communication

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	requirements.
LO3	3.1 must include the purpose and structure of technical reports; clear objectives, scope and methodology; presentation of findings, discussion, conclusions and recommendations; application of relevant documentation and data-integrity requirements. Other examples include investigation reports, validation summaries, qualification reports and analytical reports. 3.2 must include selection and use of tables, graphs, charts and structured summaries; accurate presentation of quantitative and qualitative information; appropriate units, labels and references; clarity and traceability of presented data. 3.3 must include analysis and interpretation of relevant evidence; identification of significant findings, trends or deviations; evaluation of limitations or uncertainties; conclusions supported by evidence; justified recommendations. 3.4 must include identification of audience requirements; selection of appropriate technical detail, terminology and presentation; distinction between technical findings and information required for operational or management decisions; maintenance of accuracy and objectivity.
LO4	4.1 must include identification of stakeholder information needs; selection of suitable communication methods; adaptation of language, structure and level of technical detail; consideration of confidentiality and regulatory requirements. 4.2 must include structured presentation of technical information; explanation of relevant evidence and conclusions; use of supporting documentation or visual information; appropriate responses to questions; accurate communication of recommendations and limitations. 4.3 must include communication of technical uncertainties, quality concerns or potentially adverse findings; objective and evidence-based explanations; appropriate professional language; recognition of stakeholder responsibilities; appropriate escalation and documentation. 4.4 must include assessment of communication clarity, accuracy, completeness and suitability for the audience; consideration of stakeholder understanding and feedback; implications for technical or quality decisions; justified recommendations for improving communication.

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Assessment Requirements

Assessment must demonstrate the application of specialist scientific and technical reporting 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 produce accurate and compliant technical documents, evaluate their suitability, interpret scientific information and communicate evidence-based findings.

LO2, LO3 and LO4 require evidence of applied skills. Learners must produce controlled documentation and technical reports, apply appropriate document review processes, and demonstrate effective communication of technical information.

Assessment may use authentic workplace activities or realistic technical scenarios supported by suitable scientific, operational and quality information.

Learners are not required to hold formal document approval authority, authorise controlled procedures or make final regulatory or product-release decisions.

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

Evidence may include:

- Evaluations of scientific and technical documentation requirements
- Standard operating procedures produced by the learner
- Reviews and revisions of controlled documents
- Document change records and version histories
- Technical investigation reports
- Validation or qualification summaries
- Analytical or scientific reports
- Tables, charts and graphical presentations of technical data
- Evidence-based technical conclusions and recommendations
- Presentations to technical or non-technical stakeholders
- Records or observations of technical discussions
- Evaluations of communication effectiveness
- Professional discussions supporting authentication of the evidence

LO1 – Technical writing principles

Learners should evaluate effective scientific and technical writing within regulated pharmaceutical contexts.

Assessment should require consideration of regulatory requirements, data integrity, document structure and the implications of inadequate documentation.

Learners should demonstrate understanding of how documentation supports traceability, compliance, product quality and informed decision-making.

A descriptive account of good documentation practice alone is not be sufficient to meet the evaluative requirements.

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LO2 – SOPs and controlled documentation

Learners must produce a standard operating procedure relevant to a pharmaceutical technical services activity.

The SOP must demonstrate appropriate document structure, technical accuracy, clarity and compliance with relevant documentation requirements.

Learners must also evaluate the usability of the procedure and demonstrate application of document review or revision processes.

For AC 2.4, learners may revise an existing SOP or use a realistic controlled document requiring amendment. Actual approval or implementation of the revised document is not required.

Assessment should focus on the learner's technical writing and document-control skills rather than their authority to issue controlled procedures.

LO3 – Scientific and technical reports

Learners must produce a scientific or technical report based on appropriate technical or quality evidence.

The report should demonstrate structured writing, accurate presentation of data, interpretation of findings and development of evidence-based conclusions.

The report may relate to a technical investigation, analytical evaluation, validation activity or another relevant pharmaceutical process.

Learners should evaluate the reliability and limitations of the evidence rather than simply reproduce technical results.

For AC 3.4, the learner may adapt the report or produce an appropriate summary for a different audience.

LO4 – Stakeholder communication

Learners must demonstrate the ability to communicate technical findings to appropriate stakeholders.

For AC 4.2 and 4.3, assessment should include direct evidence of communication, such as an observed technical presentation, briefing or structured discussion.

A written report alone is not sufficient to demonstrate the required communication skills.

A realistic simulation may be used where workplace communication opportunities are unavailable.

Assessment should focus on the accurate explanation of technical evidence, including uncertainties and quality concerns, rather than broader relationship-management skills.

An integrated technical reporting assignment could provide evidence across several learning outcomes, provided each criterion is clearly demonstrated.

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