Changing lives through learning

# Qualification Unit

This unit forms part of a regulated qualification.

**Unit Title:** Pharmaceutical Calculations and Batch Documentation

**Unit Reference Number:** H/652/4184

**Level:** Five (5)

**Credit Value:** 5

**Minimum Guided Learning Hours:** 35

| Learning Outcome (The Learner will): | Assessment Criterion (The Learner can): |
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| 1. Be able to perform and verify pharmaceutical calculations used in production and aseptic processing | 1.1 Perform calculations involving concentrations, dilutions, molarity and percentage strengths |
| | 1.2 Calculate the quantities of materials required for pharmaceutical batch manufacture |
| | 1.3 Apply calculations to determine pharmaceutical production and aseptic processing parameters |
| | 1.4 Verify pharmaceutical calculations and evaluate the implications of calculation errors for product quality |
| 2. Be able to analyse pharmaceutical production yields and evaluate process performance | 2.1 Calculate theoretical, actual and percentage yields using pharmaceutical production data |
| | 2.2 Analyse yield losses and identify potential causes within pharmaceutical production processes |
| | 2.3 Analyse yield trends to evaluate production efficiency and product quality |
| | 2.4 Develop justified recommendations to improve yield performance |
| 3. Be able to produce and evaluate pharmaceutical batch documentation | 3.1 Produce or complete pharmaceutical batch documentation in accordance with regulatory and data-integrity requirements |

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| | 3.2 | Identify and correct batch documentation errors using compliant amendment practices |
| | 3.3 | Verify batch documentation for completeness, accuracy, traceability and compliance |
| | 3.4 | Evaluate the contribution of batch documentation to product traceability and quality decisions |
| 4. Be able to evaluate production data and investigate discrepancies within pharmaceutical manufacturing | 4.1 | Analyse pharmaceutical production data to identify anomalies, errors and discrepancies |
| | 4.2 | Evaluate the significance of production-data discrepancies and determine appropriate responses |
| | 4.3 | Apply structured investigation methods to identify potential causes of calculation or documentation discrepancies |
| | 4.4 | Develop corrective and preventive recommendations to reduce the likelihood of recurring discrepancies |

| Indicative Content | |
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| LO1 | 1.1 must include calculations involving concentrations, dilutions, molarity and percentage strengths; appropriate units, conversions and presentation of results, including % w/v, % w/w and % v/v.<br><br>1.2 must include calculations for active pharmaceutical ingredients, excipients and other formulation components; batch-size scaling; proportional calculations; adjustment of material quantities to specified manufacturing requirements.<br><br>1.3 must include relevant production calculations, including fill volumes, overfill, line loss and flow rates, with appropriate consideration of equipment and process requirements.<br><br>Other examples include pump settings, filling-system parameters, hold-up volumes and $F_0$ calculations where relevant to the production context.<br><br>1.4 must include independent verification methods; identification and correction of calculation errors; use of appropriate precision and units; implications of inaccurate calculations for product quality, patient safety and process compliance. |
| LO2 | 2.1 must include theoretical yield, actual yield and percentage yield calculations; use of formulation and batch production data; accurate interpretation and presentation of calculated results.<br><br>2.2 must include analysis of differences between theoretical and actual yield; |

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| | identification of potential equipment, process and human-factor causes; consideration of material losses and production inefficiencies.<br>Other examples include line loss, hold-up volume, equipment retention, transfer losses and process variability.<br><br>2.3 must include comparison of yield performance across multiple batches or production periods; identification of trends and variation; evaluation of their significance for process efficiency, consistency and product quality.<br><br>2.4 must include evidence-based recommendations addressing identified yield losses or inefficiencies; consideration of process feasibility, quality requirements and anticipated improvements; appropriate measures for evaluating effectiveness. |
| LO3 | 3.1 must include applicable GMP documentation requirements; good documentation practice; ALCOA+ principles; accurate, complete, legible and contemporaneous recording of production information.<br><br>Other examples include batch manufacturing records, batch packaging records, equipment logbooks and cleaning records.<br><br>3.2 must include identification of omissions, inaccuracies and recording errors; compliant correction and amendment procedures; preservation of original information; attribution, dating and justification of corrections where required.<br><br>3.3 must include systematic review of batch documentation; verification of calculations and recorded information; identification of discrepancies or missing evidence; assessment against specified documentation and procedural requirements.<br><br>3.4 must include relationship between batch records, manufacturing history, product traceability, deviation management and batch-release processes; implications of incomplete or inaccurate records for quality assurance and regulatory compliance. |
| LO4 | 4.1 must include interpretation of relevant production and in-process control data; identification of calculation errors, data anomalies and documentation discrepancies; comparison of findings against specified requirements.<br><br>Other examples include equipment readings, fill-weight data, environmental monitoring results and production records.<br><br>4.2 must include assessment of discrepancies against product quality, patient safety, process control and data-integrity requirements; determination of significance; appropriate escalation and investigation requirements.<br><br>4.3 must include selection and application of appropriate investigation methods; review of available evidence; identification of contributory factors and potential root causes; consideration of human, procedural, equipment and system factors.<br>Other examples include 5 Whys, Ishikawa diagrams and other appropriate root-cause analysis methods.<br><br>4.4 must include recommendations linked to identified causes; proportionate corrective and preventive measures; relevant documentation, training or process-control improvements; measures for evaluating effectiveness. |

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## Assessment Requirements

Assessment must demonstrate the application of advanced pharmaceutical calculation, data-analysis and documentation skills within pharmaceutical manufacturing, aseptic processing or pharmacy technical services environments.

Learners must demonstrate Level 5 analytical and evaluative capability, including the ability to perform and verify technical calculations, interpret production performance, assess documentation accuracy and investigate discrepancies.

LO1, LO2, LO3 and LO4 require evidence of the learner applying the specified skills. Descriptions of calculation methods, documentation processes or investigation techniques alone are not sufficient.

Assessment may use authentic workplace records and data or realistic technical scenarios where access to particular production processes or documentation is unavailable.

Learners are not required to authorise manufacturing processes, approve batch documentation for product release or make final batch-disposition decisions.

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

Evidence may include:

- Completed pharmaceutical calculations with supporting workings
- Batch-size scaling and formulation calculations
- Production-yield calculations and trend analyses
- Technical reports evaluating yield performance
- Completed or simulated batch manufacturing documentation
- Documentation reviews and discrepancy records
- Production-data analysis exercises
- Deviation investigation reports
- Root-cause analysis records
- CAPA recommendations and improvement proposals
- Professional discussions supporting authentication and evaluation of technical evidence.

LO1: Learners must complete calculations independently and demonstrate appropriate methods for verifying accuracy. Assessment should use realistic pharmaceutical production scenarios involving multiple calculations or stages, rather than relying exclusively on isolated arithmetic questions.

The assessment should include sufficient complexity to demonstrate Level 5 capability. This may arise from the need to interpret production requirements, select appropriate calculations, manage multiple variables or evaluate the consequences of errors.

LO2: Learners must calculate and analyse production yields. Assessment should include sufficient production data to identify losses, investigate potential causes and evaluate trends across more than one batch or production period.

Learners should justify improvement recommendations using their analysis rather than proposing generic efficiency measures.

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LO3: Learners must produce or complete batch documentation and demonstrate appropriate checking and verification processes. Assessment should include examples of inaccurate or incomplete documentation requiring the learner to identify and correct errors.

Actual workplace batch documentation may be used where appropriate, but commercially sensitive or confidential information must be protected.

LO4: Assessment should require investigation of one or more realistic production-data or documentation discrepancies. Learners should analyse available evidence, evaluate the significance of the problem and develop justified corrective or preventive recommendations.

Where a definitive root cause cannot be established from the available evidence, learners should recognise the limitations and identify further investigation requirements.

An integrated assessment based on a pharmaceutical production scenario could generate evidence across all four learning outcomes.

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