Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Advanced Aseptic Processing and Fill-Finish Operations

Unit Reference Number: A/652/4181

Level: Five (5)

Credit Value: 7

Minimum Guided Learning Hours: 50

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand aseptic processing principles and contamination control strategies	1.1 Critically evaluate the scientific principles underpinning aseptic processing and sterility assurance
	1.2 Analyse contamination sources and evaluate strategies used to mitigate contamination risks in aseptic processing
	1.3 Interpret environmental monitoring data and evaluate its implications for aseptic processing and product quality
	1.4 Evaluate the contribution of human factors and Quality Risk Management to aseptic processing decisions
2. Understand fill-finish technologies and their operational controls	2.1 Compare fill-finish technologies and justify their suitability for different sterile manufacturing processes
	2.2 Evaluate equipment set-up, qualification and in-process control requirements for fill-finish operations
	2.3 Analyse equipment performance data and evaluate the contribution of automation and digital monitoring to fill-finish reliability
	2.4 Evaluate container-closure integrity requirements and methods used to verify integrity
3. Understand regulatory, quality and compliance requirements for aseptic and fill-finish operations	3.1 Evaluate regulatory requirements and their implications for aseptic facility and process design

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	3.2	Evaluate qualification, validation and data-integrity requirements for maintaining aseptic process control
	3.3	Evaluate documentation, deviation management and audit-readiness requirements for aseptic operations
4. Be able to apply practical aseptic techniques and operational controls	4.1	Demonstrate the preparation, set-up and in-process checking of fill-finish equipment in accordance with specified procedures
	4.2	Demonstrate aseptic manipulations and sterile material handling in accordance with contamination-control requirements
	4.3	Demonstrate gowning and de-gowning techniques appropriate to the specified cleanroom environment
5. Be able to investigate aseptic processing problems and develop justified recommendations	5.1	Analyse an aseptic processing problem to identify contributory factors and potential root causes
	5.2	Evaluate the impact of interventions and process abnormalities on sterility assurance
	5.3	Develop justified recommendations to resolve processing problems or strengthen aseptic control

Indicative Content	
LO1	1.1 must include: Microbial contamination and control; bioburden; microbial growth and inactivation; airflow dynamics; first-air protection; sterility assurance principles and relationship between process controls and product quality. 1.2 must include: Personnel, equipment, environmental and material contamination sources; contamination pathways; preventive and mitigating controls, e.g., gowning, material transfer, engineering controls and cleaning/disinfection. 1.3 must include: Viable and non-viable monitoring; alert and action levels; adverse results and trends; implications for contamination control, sterility assurance and process performance. 1.4 must include: Cleanroom behaviours; personnel movement; interventions; human-factor risks; QRM principles; risk-based selection of controls; relationship with CCS. Other examples include : FMEA, HACCP, fault-tree analysis and behavioural-risk assessments
LO2	2.1 must include: Different fill-finish technologies; advantages and limitations; process and product suitability; contamination-control implications Other examples include: RABS, isolators, automated filling lines, robotics, production capacity and cycle times.

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	2.2 must include: Equipment preparation; set-up and operational checks; calibration and qualification requirements; critical process parameters; in-process controls. Other examples include: Vial washing, depyrogenation tunnels, filling equipment, stoppering, capping, fill-weight checks and stopper placement. 2.3 must include: Equipment performance data; deviations and abnormal operating conditions; process variability; automation and digital monitoring; associated benefits, risks and limitation. Other examples include: Equipment alarms, filling variability, automated visual inspection, robotics and digital batch records 2.4 must include: Principles of CCI; relationship with product protection and sterility assurance; suitability and limitations of testing methods. Other examples include: Dye ingress, helium leak detection, high-voltage leak detection and other appropriate integrity tests
LO3	3.1 must include: GMP principles; EU GMP Annex 1; contamination control; environmental requirements; facility and operational controls. 3.2 must include: Qualification and validation lifecycle; maintaining validated state; ALCOA+; batch and equipment records; traceability and data integrity Could include: URS, DQ, IQ, OQ, PQ, process validation, electronic records and audit trails. 3.3 must include: Batch documentation; deviation and CAPA records; good documentation practice; inspection readiness; availability and accuracy of evidence; appropriate responses to findings.
LO4	4.1 must include: Relevant equipment preparation; pre-use checks; set-up; verification of equipment status; in-process checks; accurate recording and responses to identified abnormalities. 4.2 must include: Sterile transfers; aseptic material handling; maintaining first-air protection; prevention of contamination during manipulations; application of relevant procedures. 4.3 must include: Correct gowning and de-gowning sequences; garment handling; integrity checks; contamination prevention; adherence to specified cleanroom procedures.
LO5	5.1 must include: Analysis of technical and operational evidence; equipment, environmental, material and human factors; identification of potential root causes. Other examples include: Airflow disruption, equipment malfunctions, environmental excursions, pressure-cascade failures and filling-equipment problems. 5.2 must include: Planned and unplanned interventions; intervention frequency, duration and complexity; contamination risks; first-air disruption; implications for process and product quality. 5.3 must include: Evidence-based recommendations; risk assessment; proportionate corrective or preventive actions; multidisciplinary roles and communication; anticipated impact on product quality and sterility assurance.

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Assessment Requirements

Assessment must demonstrate the application of advanced specialist knowledge and, where specified, practical skills within aseptic processing and fill-finish operations.

The learner must demonstrate Level 5 analytical and evaluative capability, including the ability to interpret complex technical information, assess contamination and process risks, and justify decisions and recommendations.

LO4 requires direct evidence of practical performance. Practical assessment must be undertaken using appropriate equipment, facilities or suitable simulation arrangements and under relevant safety and supervision controls.

The unit does not confer occupational competence in its own right or authorise learners to undertake regulated aseptic production activities independently.

Evidence may include practical observations, authenticated workplace records, simulated technical activities, environmental or equipment data analysis, technical evaluations, case studies, investigation reports, professional discussions and improvement proposals.

For LO1–LO3, assessment should demonstrate technical understanding through analysis and evaluation rather than knowledge recall alone.

For LO4, all three practical criteria require authenticated evidence of performance. A written assignment or professional discussion alone is not sufficient evidence. Practical simulation is acceptable where it genuinely demonstrates the specified skills and controls.

For LO5, learners should investigate a realistic processing problem and make defensible recommendations. They are not required to implement or authorise the recommended actions.

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