Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Sterilisation, Depyrogenation and Materials Compatibility

Unit Reference Number: F/652/4183

Level: Five (5)

Credit Value: 6

Minimum Guided Learning Hours: 45

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand sterilisation principles, technologies and regulatory requirements	1.1 Compare sterilisation technologies and justify their suitability for different pharmaceutical products and materials
	1.2 Evaluate regulatory expectations for sterilisation validation and routine process monitoring
	1.3 Evaluate the role of sterilisation within a contamination control strategy
	1.4 Compare sterilisation technologies and justify their suitability for different pharmaceutical products and materials
2. Understand depyrogenation processes and their application in sterile manufacturing	2.1 Evaluate the scientific principles underpinning depyrogenation and pyrogen control
	2.2 Compare depyrogenation methods and justify their suitability for different applications
	2.3 Evaluate depyrogenation validation and monitoring requirements
	2.4 Evaluate the contribution of depyrogenation to sterile product quality and assurance
3. Understand the compatibility of pharmaceutical materials with sterilisation and depyrogenation processes	3.1 Evaluate how pharmaceutical materials respond to sterilisation and depyrogenation conditions

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	3.2	Analyse material failure mechanisms associated with sterilisation and depyrogenation processes
	3.3	Evaluate extractables, leachables and container-closure integrity considerations associated with material compatibility
	3.4	Justify the selection of sterilisation or depyrogenation methods for specified pharmaceutical materials
4. Be able to evaluate sterilisation and depyrogenation process performance and investigate failures	4.1	Analyse sterilisation and depyrogenation process data against validated requirements
	4.2	Apply structured investigation methods to identify potential causes of sterilisation or depyrogenation process failures
	4.3	Evaluate the significance of process failures and determine appropriate corrective or preventive responses
	4.4	Develop justified recommendations to maintain or improve sterilisation and depyrogenation process control

Indicative Content	
LO1	1.1 must include microbial inactivation kinetics, D-values, Z-values, F_0 concepts and sterility assurance levels (SAL), including their relevance to sterilisation effectiveness. 1.2 must include the principles, applications, advantages and limitations of moist heat, dry heat, sterilising filtration, radiation and gas sterilisation. Other examples include autoclaving, gamma irradiation, electron-beam sterilisation, ethylene oxide and sterilising-grade membrane filtration. 1.3 must include relevant GMP requirements, qualification and validation principles, process monitoring, acceptance criteria, requalification and maintenance of the validated state. Other examples include biological indicators, temperature mapping, load qualification, filter-integrity testing and routine cycle monitoring. 1.4 must include the relationship between sterilisation, bioburden control, contamination prevention, product protection and sterility assurance, including the limitations of sterilisation as an individual contamination-control measure.
LO2	2.1 must include pyrogens and bacterial endotoxins, their sources and associated product risks, principles of endotoxin inactivation or removal, and the distinction between sterilisation and depyrogenation. 2.2 must include dry-heat depyrogenation, chemical approaches and other relevant endotoxin-reduction methods, including their applications, limitations

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	and compatibility with pharmaceutical materials. Other examples include dry-heat tunnels, alkaline or oxidising treatments and appropriate filtration-based endotoxin removal processes. 2.3 must include critical process parameters, endotoxin challenge studies, endotoxin reduction factors, acceptance criteria and evidence required to demonstrate effective depyrogenation. Other examples include temperature distribution, exposure times, endotoxin testing and routine monitoring of validated cycles. 2.4 must include the relationship between pyrogen control, process design, material treatment, contamination control and patient safety, including the limitations of different depyrogenation approaches.
LO3	3.1 must include the properties and behaviour of glass, elastomers, plastics and metals under relevant thermal, chemical and radiation conditions. Other examples include thermal shock, glass delamination, elastomer degradation, plastic deformation and changes in material permeability. 3.2 must include the effects of thermal, chemical and radiation stress on material integrity and performance, including degradation, deformation, embrittlement and loss of barrier properties. 3.3 must include extractables and leachables principles, risks arising from material-process interactions, container-closure integrity and implications for product quality and patient safety. 3.4 must include evaluation of material characteristics, process effectiveness, compatibility risks, product quality requirements and relevant regulatory considerations.
LO4	4.1 must include interpretation of relevant process parameters, cycle records, monitoring results and acceptance criteria; identification of deviations or non-conforming results. Other examples include temperature profiles, exposure times, F_0 data, biological indicator results, endotoxin reduction data and load configurations. 4.2 must include investigation of process deviations; evaluation of available technical evidence; identification of contributory factors and potential root causes; consideration of equipment, process, material and operational factors. Other examples include temperature-mapping failures, biological indicator failures, equipment malfunctions, inappropriate load configurations and incomplete depyrogenation. 4.3 must include assessment of product quality, sterility assurance and patient-safety risks; deviation significance; investigation and escalation requirements; risk-based selection of corrective and preventive actions. 4.4 must include evidence-based recommendations; relevant validation or requalification requirements; CAPA effectiveness measures; integration with change control, quality management systems and contamination control strategies. Other examples include cycle optimisation, revised load configurations,

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	equipment maintenance, procedural changes and additional process monitoring.

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Assessment Requirements

Assessment must demonstrate the application of advanced specialist knowledge to sterilisation, depyrogenation and materials compatibility within pharmaceutical manufacturing, aseptic services or pharmacy technical services environments.

Learners must demonstrate Level 5 analytical and evaluative capability, including the ability to interpret technical and validation data, assess material compatibility, investigate process failures and justify appropriate recommendations.

LO4 requires evidence of applying analytical and investigative methodologies. Learners must analyse relevant process evidence and demonstrate their ability to investigate problems and make justified technical recommendations.

Assessment may draw on authentic workplace activities or realistic technical scenarios supported by appropriate process data, validation records and other evidence.

Learners are not required to independently operate or validate sterilisation and depyrogenation equipment, authorise changes to validated processes or make final product-release decisions.

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

Evidence may include:

- Technical comparisons of sterilisation and depyrogenation methods
- Evaluations of material compatibility and process suitability
- Interpretation of sterilisation and depyrogenation cycle data
- Reviews of qualification and validation evidence
- Materials compatibility case studies
- Investigation reports relating to process failures or deviations
- Quality risk assessments
- CAPA plans and process improvement recommendations
- Professional discussions supported by technical evidence
- Authenticated workplace records or technical projects

LO1: Learners should evaluate the scientific principles and suitability of sterilisation technologies, including their limitations and the factors affecting process effectiveness. Assessment should go beyond describing methods and require justified comparisons and conclusions.

LO2: Learners should demonstrate an understanding of the distinction between sterilisation and depyrogenation. Assessment should include evaluation of depyrogenation methods and the evidence required to demonstrate their effectiveness.

LO3: Assessment should use realistic material and process scenarios requiring learners to evaluate compatibility risks and justify suitable methods. Learners should consider the consequences of material degradation or loss of integrity for product quality and patient safety.

LO4: Learners must interpret relevant process data and investigate at least one realistic sterilisation or depyrogenation problem. The evidence should allow them to identify deviations, examine potential causes, assess risks and develop justified

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recommendations.

Actual implementation of corrective actions, equipment requalification or process changes is not required. Where recommendations are based on simulated scenarios, the technical data and operating conditions must be sufficiently realistic to support meaningful Level 5 assessment.

Integrated assessment may be used where a technical investigation or process evaluation provides evidence against multiple criteria, provided achievement of each criterion can be clearly identified.

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