

LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 11737 — Sterilization of Medical Devices Microbiological Methods

ISO Certification Programme



LAPT — London Academy of Professional Training

Address 85 Great Portland Street, W1W 7LT, London, United Kingdom

Email info@lapt.org

Telephone +44 7513 283044

Web lapt.org

Reference HL-BIO-11737 • ISO Health

UKPRN 10067351 • Registered in England and Wales, company 4984798

AT A GLANCE

REFERENCE	HL-BIO-11737
AWARD	Certificate
ASSESSMENT	430 marks — 258 to pass (60%)
PREREQUISITES	None
VALIDITY	Lifetime
AWARDING BODY	LAPT — London Academy of Professional Training

CURRICULUM

1

Advanced Problem-Solving in Sterilization

5 chapters · 30 classes65 marks

• 1 Fundamentals of Sterilization Microbiology — 6 classes

› 1.1 Explore Key Microbial Agents in Sterilization Processes

› 1.2 Analyze the Mechanisms of Microbial Resistance

› 1.3 Identify Sterilization Methods and Their Microbiological Impact

› 1.4 Examine the Role of Validation in Sterilization Microbiology

› 1.5 Assess Common Microbiological Testing Protocols

› 1.6 Apply Problem-Solving Strategies to Sterilization Challenges

• 2 ISO 11737 Standards and Compliance — 6 classes

› 2.1 Analyze the Key Principles of ISO 11737 Standards

› 2.2 Identify Core Microbiological Methods for Sterilization

› 2.3 Evaluate Compliance Requirements for Medical Device Sterilization

› 2.4 Investigate Common Challenges in ISO 11737 Implementation

› 2.5 Develop Strategies for Effective Problem-Solving in Sterilization

› 2.6 Apply ISO 11737 Standards in Real-World Scenarios

• 3 Advanced Techniques in Sterilization Validation — 6 classes

› 3.1 Analyze Current Sterilization Validation Techniques

› 3.2 Explore Advanced Microbiological Methods in Sterilization

› 3.3 Implement Risk Assessment Strategies for Sterilization Validation

› 3.4 Evaluate Environmental Factors Influencing Sterilization Success

› 3.5 Integrate Validation Protocols with ISO 11737 Standards

› 3.6 Design a Comprehensive Sterilization Validation Plan

• 4 Troubleshooting Common Sterilization Issues — 6 classes

› 4.1 Identify Common Sterilization Failures in Medical Devices

› 4.2 Analyze Microbial Load and Its Impact on Sterilization Efficacy

› 4.3 Evaluate Equipment Functionality to Diagnose Procedural Errors

› 4.4 Investigate Environmental Factors Affecting Sterilization Processes

› 4.5 Implement Corrective Actions for Identified Sterilization Issues

› 4.6 Develop Best Practices for Continuous Improvement in Sterilization Protocols

• 5 Leadership Strategies in Sterilization Quality Assurance — 6 classes

› 5.1 Define Key Leadership Roles in Sterilization Quality Assurance

› 5.2 Analyze Effective Communication Techniques in Quality Management

› 5.3 Identify Challenges in Sterilization Processes and Solutions

› 5.4 Implement Continuous Improvement Strategies in Sterilization

› 5.5 Develop a Team-Based Approach to Quality Assurance

› 5.6 Evaluate the Impact of Leadership on Sterilization Outcomes

• 1 Understanding ISO 11737 Standards and Principles — 6 classes

- › 1.1 Define the Key Principles of ISO 11737 Standards
- › 1.2 Identify the Importance of Microbiological Methods in Sterilization
- › 1.3 Explain the Role of Compliance Requirements in ISO 11737
- › 1.4 Analyze the Impact of Non-Compliance with ISO 11737 Standards
- › 1.5 Illustrate the Best Practices for Implementing ISO 11737 in Medical Devices
- › 1.6 Develop a Compliance Checklist for ISO 11737 Implementation

• 2 Microbiological Methods in Sterilization Practices — 6 classes

- › 2.1 Understand the Importance of Microbiological Methods in Sterilization
- › 2.2 Identify Key ISO Standards Relevant to Microbiological Testing
- › 2.3 Explore Key Microorganisms Used in Sterilization Validation
- › 2.4 Analyze Methods for Microbiological Testing in Sterilization Processes
- › 2.5 Evaluate Compliance Requirements for Microbiological Methods
- › 2.6 Implement Best Practices for Documentation and Reporting in Microbiological Methods

• 3 Regulatory Compliance and Quality Management Systems — 6 classes

- › 3.1 Understand ISO 11737: Key Principles and Objectives
- › 3.2 Explore Regulatory Compliance: Key Requirements and Frameworks
- › 3.3 Identify Quality Management Systems: Roles and Importance
- › 3.4 Assess the Impact of Non-Compliance: Risks and Consequences
- › 3.5 Implement Effective Quality Management: Tools and Strategies
- › 3.6 Develop an Action Plan for Continuous Compliance Improvement

• 4 Risk Assessment and Management in Sterilization Protocols — 6 classes

- › 4.1 Identify Key Risks in Sterilization Processes
- › 4.2 Analyze Potential Contamination Sources in Medical Devices
- › 4.3 Evaluate Current Sterilization Methods and Their Effectiveness
- › 4.4 Develop a Comprehensive Risk Management Plan
- › 4.5 Implement Mitigation Strategies for Identified Risks
- › 4.6 Review and Revise Risk Assessments Regularly

• 5 Implementing and Auditing Compliance to ISO 11737 — 6 classes

- › 5.1 Understand the Key Components of ISO 11737 Standards
- › 5.2 Identify the Roles and Responsibilities in Sterilization Processes
- › 5.3 Develop a Compliance Checklist for ISO 11737 Implementation
- › 5.4 Establish Best Practices for Sterilization Audits
- › 5.5 Analyze Common Non-Conformities in ISO 11737 Compliance
- › 5.6 Conduct a Mock Audit to Assess ISO 11737 Compliance

• 1 Understanding Leadership Styles in Biotechnology — 6 classes

- › 1.1 Identify Key Leadership Styles in Biotechnology
- › 1.2 Analyze the Impact of Leadership Styles on Team Dynamics
- › 1.3 Explore Effective Communication Techniques for Leaders
- › 1.4 Assess Situational Leadership in the Context of Biotechnology
- › 1.5 Develop Strategies for Leading Diverse Teams
- › 1.6 Apply Leadership Styles to Real-World Biotechnology Scenarios

• 2 Building High-Performing Teams in the Sterilization Sector — 6 classes

- › 2.1 Identify Key Characteristics of High-Performing Teams in Sterilization
- › 2.2 Assess Team Roles and Responsibilities for Effective Workflows
- › 2.3 Develop Strategies for Effective Communication Among Team Members
- › 2.4 Foster Collaboration and Trust within Sterilization Teams
- › 2.5 Implement Problem-Solving Techniques to Overcome Team Challenges
- › 2.6 Evaluate Team Performance Metrics and Continuous Improvement Strategies

• 3 Effective Communication and Conflict Resolution — 6 classes

- › 3.1 Analyze Communication Styles in Leadership
- › 3.2 Identify Barriers to Effective Communication
- › 3.3 Employ Active Listening Techniques
- › 3.4 Develop Strategies for Resolving Conflicts
- › 3.5 Practice Role-Playing Conflict Scenarios
- › 3.6 Evaluate Team Communication for Continuous Improvement

• 4 Strategic Decision-Making for ISO Compliance — 6 classes

- › 4.1 Analyze ISO 11737 Standards for Effective Leadership
- › 4.2 Identify Key Stakeholders in ISO Compliance Decision-Making
- › 4.3 Develop Strategic Criteria for Evaluating Microbiological Methods
- › 4.4 Formulate Collaborative Approaches to Team Management in ISO Processes
- › 4.5 Implement Decision-Making Tools for Compliance Strategy
- › 4.6 Evaluate Outcomes of ISO Compliance Decisions for Continuous Improvement

• 5 Leading Change in a Regulated Environment — 6 classes

- › 5.1 Assessing Change Readiness in a Regulated Environment
- › 5.2 Identifying Key Stakeholders for Successful Change Implementation
- › 5.3 Developing a Strategic Change Communication Plan
- › 5.4 Cultivating a Culture of Compliance and Adaptability
- › 5.5 Measuring the Impact of Change on Team Dynamics
- › 5.6 Leading Teams Through Resistance to Change in ISO Contexts

• 1 Fundamentals of Microbiology in Sterilization — 6 classes

- › 1.1 Identify Key Microbiological Concepts in Sterilization
- › 1.2 Explain the Role of Microorganisms in Medical Device Contamination
- › 1.3 Analyze Common Microbiological Methods Used in Sterilization
- › 1.4 Discuss the Principles of Disinfection vs. Sterilization
- › 1.5 Evaluate the Importance of Validation in Sterilization Processes
- › 1.6 Apply Microbiological Knowledge to Improve Sterilization Protocols

• 2 Mechanisms of Sterilization Methods — 6 classes

- › 2.1 Explore Physical Sterilization Mechanisms
- › 2.2 Investigate Chemical Sterilization Agents and Their Effects
- › 2.3 Analyze Biological Indicators of Sterilization Efficacy
- › 2.4 Understand the Role of Temperature and Pressure in Sterilization
- › 2.5 Examine the Limitations and Challenges of Sterilization Methods
- › 2.6 Apply Microbiological Principles to Assess Sterilization Techniques

• 3 Microbial Risk Assessment in Sterilization Processes — 6 classes

- › 3.1 Identify Key Microbial Threats in Sterilization
- › 3.2 Analyze the Role of Biofilms in Sterilization Failure
- › 3.3 Evaluate Microbial Load and Its Impact on Sterilization Efficacy
- › 3.4 Assess the Influence of Environmental Factors on Microbial Survival
- › 3.5 Develop Risk Mitigation Strategies for Sterilization Processes
- › 3.6 Implement a Microbial Risk Assessment Framework for Clinical Settings

• 4 Validation of Sterilization Processes — 6 classes

- › 4.1 Explain key concepts of sterilization validation
- › 4.2 Identify the importance of biological indicators
- › 4.3 Discuss the role of chemical indicators in sterilization
- › 4.4 Outline the steps in developing a validation protocol
- › 4.5 Analyze case studies of sterilization process failures
- › 4.6 Implement a validation process for a specific medical device

• 5 Quality Control and Assurance in Sterilization — 6 classes

- › 5.1 Define Key Quality Control Concepts in Sterilization
- › 5.2 Identify Microbiological Methods for Quality Assurance
- › 5.3 Analyze the Role of Environmental Monitoring in Sterilization
- › 5.4 Evaluate the Effectiveness of Sterilization Processes
- › 5.5 Implement Standard Operating Procedures for Quality Control
- › 5.6 Develop a Quality Assurance Plan for Sterilization Protocols

• 1 Understanding Quality Management Systems in Biotechnology — 6 classes

- › 1.1 Define and Explain Quality Management Systems in Biotechnology
- › 1.2 Identify Key Components of ISO 11737 Standards
- › 1.3 Compare Quality Management Practices Across Biotech Sectors
- › 1.4 Assess the Role of Microbiological Methods in Sterilization
- › 1.5 Implement Best Practices for Quality Control in Biotechnology
- › 1.6 Evaluate Case Studies on Quality Management Successes and Failures

• 2 ISO 11737 Standards and Their Application — 6 classes

- › 2.1 Explain the Importance of ISO 11737 in Medical Device Sterilization
- › 2.2 Identify Key Principles of Microbiological Methods in Biomaterials
- › 2.3 Discuss the Roles and Responsibilities in Quality Management Systems
- › 2.4 Analyze ISO 11737 Standards and Their Core Requirements
- › 2.5 Evaluate Case Studies on ISO 11737 Compliance in Biotechnology
- › 2.6 Develop an Action Plan for Implementing ISO 11737 Standards in Practice

• 3 Risk Management Principles in Sterilization Processes — 6 classes

- › 3.1 Identify Key Risks in Sterilization Processes
- › 3.2 Assess Risk Factors Affecting Sterilization Efficacy
- › 3.3 Develop Risk Mitigation Strategies for Medical Device Sterilization
- › 3.4 Implement Quality Control Measures in Sterilization Protocols
- › 3.5 Monitor and Evaluate the Effectiveness of Sterilization Risks
- › 3.6 Communicate Risk Management Findings to Stakeholders

• 4 Implementing and Sustaining an Effective QMS — 6 classes

- › 4.1 Define Key Concepts in Quality Management Systems
- › 4.2 Identify Regulatory Requirements for ISO 11737 Compliance
- › 4.3 Develop Standard Operating Procedures for Sterilization Processes
- › 4.4 Implement Risk Management Strategies in QMS
- › 4.5 Measure Performance Metrics in Quality Management
- › 4.6 Create a Continuous Improvement Plan for Sustaining QMS

• 5 Auditing and Compliance in Biotechnology Quality Systems — 6 classes

- › 5.1 Identify Key Principles of Auditing in Biotechnology Quality Systems
- › 5.2 Assess Compliance with ISO 11737 Standards in Medical Device Sterilization
- › 5.3 Analyze Common Non-Conformities in Biotechnology Audits
- › 5.4 Develop an Effective Audit Checklist for Quality Management Systems
- › 5.5 Implement Corrective Actions Based on Audit Findings
- › 5.6 Evaluate Continuous Improvement Strategies in Biotechnology Quality Compliance

• 1 Fundamentals of Sterilization in Medical Devices — 6 classes

- › 1.1 Define Sterilization Principles in Medical Devices
- › 1.2 Explore Different Sterilization Methods and Their Applications
- › 1.3 Identify Key Microbial Challenges in Sterilization Processes
- › 1.4 Discuss Regulatory Standards for Sterilization Validation
- › 1.5 Analyze Testing Methods for Sterilization Efficacy
- › 1.6 Implement Quality Control Measures in Sterilization Practices

• 2 Microbiological Testing Methods for Sterilization Validation — 6 classes

- › 2.1 Identify Key Microbiological Testing Methods for Sterilization
- › 2.2 Explain the Role of Bioburden Testing in Sterilization Validation
- › 2.3 Evaluate the Efficacy of Different Microbial Indicators
- › 2.4 Summarize the Process of Conducting a Sterility Test
- › 2.5 Compare Validation Protocols for Various Sterilization Methods
- › 2.6 Design a Microbiological Testing Protocol for a Medical Device

• 3 Designing Sterilization Validation Protocols — 6 classes

- › 3.1 Analyze the Requirements for Sterilization Validation Protocols
- › 3.2 Identify Key Microbiological Methods for Testing Sterilization Efficacy
- › 3.3 Develop Standard Operating Procedures for Sterilization Testing
- › 3.4 Design Experiments to Validate Sterilization Processes
- › 3.5 Assess Data Collection Techniques for Sterilization Validation
- › 3.6 Evaluate Results and Document Findings for Sterilization Protocols

• 4 Interpreting and Reporting Sterilization Validation Results — 6 classes

- › 4.1 Analyze Sterilization Validation Protocols
- › 4.2 Identify Key Microbiological Indicators in Validation
- › 4.3 Evaluate Sterilization Results Against Acceptance Criteria
- › 4.4 Interpret Data Trends in Sterilization Efficacy Testing
- › 4.5 Communicate Validation Results Effectively to Stakeholders
- › 4.6 Develop Recommendations Based on Interpretation of Results

• 5 Regulatory Compliance and Quality Assurance in Sterilization — 6 classes

- › 5.1 Analyze Regulatory Standards for Sterilization
- › 5.2 Evaluate Quality Assurance Protocols in Medical Device Sterilization
- › 5.3 Identify Key Microbiological Testing Methods
- › 5.4 Apply Validation Techniques for Sterilization Processes
- › 5.5 Review Non-conformities and Compliance Issues in Sterilization
- › 5.6 Develop a Continuous Improvement Plan for Sterilization Quality