

LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 11607 — Packaging for Terminally Sterilized Medical Devices

ISO Certification Programme



LAPT — London Academy of Professional Training

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Reference HL-EQP-11607 • ISO Health

UKPRN 10067351 • Registered in England and Wales, company 4984798

AT A GLANCE

REFERENCE	HL-EQP-11607
AWARD	Certificate
ASSESSMENT	430 marks — 258 to pass (60%)
PREREQUISITES	None
VALIDITY	Lifetime
AWARDING BODY	LAPT — London Academy of Professional Training

CURRICULUM

1 ISO 11607 Regulations 5 chapters · 30 classes 85 marks • 1 Fundamentals of ISO 11607: Understanding Regulatory Frameworks — 6 classes › 1.1 Explore the Importance of ISO 11607 in Medical Device Packaging › 1.2 Identify Key Components of the ISO 11607 Regulatory Framework › 1.3 Analyze the Relationship Between ISO 11607 and International Standards › 1.4 Compare ISO 11607 with Other Regulatory Requirements › 1.5 Assess the Impact of Compliance on Medical Device Safety and Efficacy › 1.6 Implement Best Practices for Adhering to ISO 11607 Standards • 2 Packaging Design Requirements for Terminally Sterilized Medical Devices — 6 classes › 2.1 Identify Key Packaging Design Principles for Medical Devices › 2.2 Analyze Material Selection Criteria for Sterile Packaging › 2.3 Evaluate Barrier Properties Essential for Packaging Integrity › 2.4 Assess the Role of Packaging Design in Sterilization Processes › 2.5 Implement Compliance Verification Strategies for Packaging Designs › 2.6 Develop a Packaging Design Plan Aligned with ISO 11607 Standards • 3 Validation of Packaging Processes for Sterility Assurance — 6 classes › 3.1 Outline the Importance of Validation in Packaging Processes › 3.2 Identify Key Standards and Regulations in ISO 11607 › 3.3 Describe the Packaging Process for Terminally Sterilized Medical Devices › 3.4 Explain the Principles of Sterility Assurance in Packaging › 3.5 Apply Validation Techniques for Packaging Processes › 3.6 Assess Compliance through Documentation and Review • 4 Risk Management in Packaging for Terminally Sterilized Devices — 6 classes › 4.1 Identify Key Risks in Packaging for Terminally Sterilized Devices › 4.2 Analyze the Impact of Packaging Risks on Sterilization Outcomes › 4.3 Develop Risk Mitigation Strategies for Packaging Design › 4.4 Implement Risk Control Measures in Packaging Processes › 4.5 Evaluate the Effectiveness of Risk Management Practices › 4.6 Communicate Risk Management Findings to Stakeholders • 5 Quality Control and Assurance in ISO 11607 Compliance — 6 classes › 5.1 Explore Key Components of Quality Control in ISO 11607 › 5.2 Analyze Risk Management Practices Relevant to Quality Assurance › 5.3 Examine the Role of Validation in Packaging Processes › 5.4 Assess Compliance with Testing Requirements in ISO 11607 › 5.5 Implement Best Practices for Quality Control Documentation › 5.6 Develop a Continuous Improvement Plan for Quality Assurance

2

Materials Science in Packaging

0 chapters 65 marks

• 1 Fundamentals of Packaging Design for Medical Devices — 6 classes

- › 1.1 Identify Key Principles of Medical Device Packaging Design
- › 1.2 Analyze the Importance of Sterilization in Packaging
- › 1.3 Explore Materials Used in Medical Device Packaging
- › 1.4 Assess Design Considerations for User Safety and Compliance
- › 1.5 Evaluate Packaging Integrity and Performance Testing Methods
- › 1.6 Apply ISO 11607 Standards to Real-world Packaging Scenarios

• 2 Materials Selection for Sterile Packaging — 6 classes

- › 2.1 Identify Key Materials for Sterile Packaging
- › 2.2 Analyze Material Properties for Sterilization Compatibility
- › 2.3 Evaluate Performance Criteria in Packaging Design
- › 2.4 Integrate Regulatory Requirements in Material Selection
- › 2.5 Compare Biodegradable Options for Sustainable Packaging
- › 2.6 Develop a Material Selection Strategy for Medical Devices

• 3 Design Considerations for Sterilization Methods — 6 classes

- › 3.1 Identify Key Sterilization Methods for Medical Device Packaging
- › 3.2 Analyze Material Properties Impacting Sterilization Efficacy
- › 3.3 Evaluate Packaging Configuration for Compatibility with Sterilization
- › 3.4 Apply Design Principles for Preventing Sterilization Contamination
- › 3.5 Develop Strategies for Validating Packaging Integrity Post-Sterilization
- › 3.6 Create a Risk Assessment for Packaging Design During Sterilization Processes

• 4 Testing and Validation of Packaging Systems — 6 classes

- › 4.1 Identify Key Standards for Testing Packaging Systems
- › 4.2 Analyze Methods for Validation of Packaging for Sterilized Devices
- › 4.3 Evaluate Environmental Impact on Packaging Integrity
- › 4.4 Conduct Performance Testing of Packaging Materials
- › 4.5 Interpret Test Results and Validate Packaging Efficacy
- › 4.6 Develop a Compliance Strategy for Continuous Improvement

• 5 Compliance and Quality Control in Packaging Design — 6 classes

- › 5.1 Analyze Regulatory Standards for Packaging Compliance
- › 5.2 Examine Quality Control Processes in Packaging Design
- › 5.3 Identify Key Factors in Material Selection for Medical Packaging
- › 5.4 Evaluate Testing Methods for Sterilization Validation
- › 5.5 Develop a Quality Assurance Plan for Packaging Systems
- › 5.6 Implement Continuous Improvement Strategies in Packaging Quality