LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 13485 — Medical Devices Quality Management Systems

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-EQP-13485 • ISO Health

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6	30	180	430	60%	Lifetime
SUBJECTS	CHAPTERS	CLASSES	TOTAL MARKS	PASS MARK	VALIDITY

AT A GLANCE

REFERENCE	**HL-EQP-13485**
AWARD	**Certificate**
ASSESSMENT	**430 marks — 258 to pass (60%)**
PREREQUISITES	**None**
VALIDITY	**Lifetime**
AWARDING BODY	**LAPT — London Academy of Professional Training**

CURRICULUM

1 Continuous Improvement Strategies

5 chapters · 30 classes · **85 marks**

• 1 Understanding Continuous Improvement Principles in Healthcare — 6 classes

- › 1.1 Define Continuous Improvement in Healthcare Settings
- › 1.2 Identify Key Principles of Continuous Improvement
- › 1.3 Explore Tools for Continuous Improvement in Medical Devices
- › 1.4 Analyze Case Studies of Successful Continuous Improvement
- › 1.5 Develop Strategies for Implementing Continuous Improvement
- › 1.6 Evaluate the Impact of Continuous Improvement on Patient Outcomes

• 2 Key Methodologies for Continuous Improvement in Medical Devices — 6 classes

- › 2.1 Identify Key Continuous Improvement Methodologies in Medical Device Quality
- › 2.2 Analyze the Role of Lean Six Sigma in Enhancing Quality Management
- › 2.3 Implement Plan-Do-Check-Act Cycle for Effective Process Improvement
- › 2.4 Evaluate Root Cause Analysis Techniques for Medical Device Issues
- › 2.5 Develop Action Plans Using Kaizen Principles for Continuous Improvement
- › 2.6 Measure the Impact of Continuous Improvement on Quality Assurance Metrics

• 3 Data-Driven Decision Making for Quality Enhancement — 6 classes

- › 3.1 Analyze Data Sources for Quality Insights
- › 3.2 Interpret Key Performance Indicators in Medical Device Context
- › 3.3 Utilize Statistical Tools for Quality Improvement
- › 3.4 Identify Trends and Patterns in Quality Data
- › 3.5 Develop Actionable Strategies Based on Data Analysis
- › 3.6 Implement Continuous Improvement Initiatives Using Data

• 4 Implementing Continuous Improvement Initiatives in ISO 13485 — 6 classes

- › 4.1 Identify Key Areas for Continuous Improvement in ISO 13485
- › 4.2 Develop a Continuous Improvement Plan for Medical Device Quality
- › 4.3 Implement Lean Principles in Medical Device Manufacturing
- › 4.4 Utilize Root Cause Analysis to Drive Quality Improvements
- › 4.5 Engage Teams in Continuous Improvement through Training and Workshops
- › 4.6 Measure and Evaluate the Impact of Continuous Improvement Initiatives

• 5 Evaluating and Sustaining Continuous Improvement Outcomes — 6 classes

- › 5.1 Identify Key Performance Indicators for Continuous Improvement
- › 5.2 Analyze Data to Evaluate Continuous Improvement Outcomes
- › 5.3 Implement Feedback Mechanisms to Sustain Improvements
- › 5.4 Develop Action Plans Based on Evaluation Results
- › 5.5 Cultivate a Culture of Continuous Improvement in Teams
- › 5.6 Review and Adapt Strategies for Long-term Success

2 Introduction to ISO 13485

5 chapters · 30 classes **85 marks**

• 1 Foundations of ISO 13485: Understanding Quality Management Systems in Medical Devices — 6 classes

- 1.1 Define Quality Management Systems in Medical Devices
- 1.2 Identify Key Principles of ISO 13485
- 1.3 Explore the Role of Documentation in Quality Management
- 1.4 Assess the Importance of Risk Management in ISO 13485
- 1.5 Examine the Structure of ISO 13485 Standards
- 1.6 Apply ISO 13485 Principles to Real-World Medical Device Scenarios

• 2 Key Principles and Terminology of ISO 13485 — 6 classes

- 2.1 Define Key Terms in ISO 13485
- 2.2 Explore the Structure of ISO 13485
- 2.3 Understand the Importance of Quality Management Systems
- 2.4 Identify the Roles of Leadership in ISO 13485
- 2.5 Analyze the Relationship Between ISO 13485 and Regulatory Compliance
- 2.6 Apply Key Principles of ISO 13485 to Real-world Scenarios

• 3 Document Control and Record Management in ISO 13485 — 6 classes

- 3.1 Understand the Importance of Document Control in ISO 13485
- 3.2 Identify Key Components of ISO 13485 Document Management Procedures
- 3.3 Describe Record Management Requirements for Medical Device Compliance
- 3.4 Implement Effective Document Control Processes in Your Organization
- 3.5 Evaluate Document Control Systems for Continuous Improvement
- 3.6 Develop a Training Plan for Staff on Document and Record Management

• 4 Roles and Responsibilities in ISO 13485 Implementation — 6 classes

- 4.1 Identify Key Roles in ISO 13485 Implementation
- 4.2 Understand Leadership Responsibilities in Quality Management
- 4.3 Define the Role of Top Management in ISO 13485
- 4.4 Analyze Responsibilities of Quality Managers in ISO 13485
- 4.5 Assess the Role of Employees in Quality Culture
- 4.6 Develop an Action Plan for Role Assignment in ISO 13485

• 5 Internal Audits and Continuous Improvement in ISO 13485 — 6 classes

- 5.1 Understand the Purpose of Internal Audits in ISO 13485
- 5.2 Identify Key Elements of an Effective Internal Audit Process
- 5.3 Learn How to Plan and Prepare for an Internal Audit
- 5.4 Conduct a Mock Internal Audit Simulation
- 5.5 Analyze Audit Findings for Continuous Improvement
- 5.6 Develop an Action Plan Based on Audit Outcomes

3 Leadership in Quality Management

5 chapters · 30 classes **45 marks**

• 1 Understanding Leadership Roles in Quality Management Systems for Medical Devices — 6 classes

- 1.1 Describe the Importance of Leadership in Quality Management Systems
- 1.2 Identify Key Leadership Roles in Medical Device Quality Management
- 1.3 Analyze the Impact of Leadership on Quality Culture in Organizations
- 1.4 Explore Leadership Strategies for Effective Quality Management
- 1.5 Evaluate the Challenges Leaders Face in Quality Management Systems
- 1.6 Develop an Action Plan for Enhancing Leadership within Quality Teams

• 2 Regulatory Landscape and its Impact on Leadership in ISO 13485 — 6 classes

- 2.1 Analyze the Regulatory Landscape for ISO 13485 Compliance
- 2.2 Identify Key Leadership Roles in Quality Management Systems
- 2.3 Evaluate the Impact of Regulatory Changes on Leadership Strategies
- 2.4 Develop Leadership Competencies for Managing Compliance Challenges
- 2.5 Implement Best Practices for Maintaining ISO 13485 Standards
- 2.6 Assess the Effectiveness of Leadership Approaches in Quality Management

• 3 Building a Quality-Driven Culture within Medical Device Organizations — 6 classes

- 3.1 Define and Understand Quality-Driven Culture in Medical Devices
- 3.2 Identify Key Leadership Traits for Fostering Quality Management
- 3.3 Develop Strategies for Employee Engagement in Quality Practices
- 3.4 Implement Effective Communication Channels to Promote Quality Values
- 3.5 Assess and Monitor Quality Performance Metrics in Teams
- 3.6 Create Action Plans to Sustain a Quality-Driven Culture

• 4 Leadership Strategies for Effective Risk Management in Quality Assurance — 6 classes

- 4.1 Analyze Leadership Roles in Risk Management
- 4.2 Identify Key Risk Management Strategies in Quality Assurance
- 4.3 Develop a Risk Assessment Framework for Medical Devices
- 4.4 Implement Effective Communication Techniques for Risk Awareness
- 4.5 Evaluate Leadership Practices that Enhance Risk Mitigation
- 4.6 Create an Action Plan for Continuous Improvement in Risk Management

• 5 Driving Continuous Improvement through Leadership in Quality Management — 6 classes

- 5.1 Identify Key Principles of Continuous Improvement in Quality Management
- 5.2 Analyze Leadership Styles that Promote Quality Enhancement
- 5.3 Develop Strategies for Engaging Teams in Quality Initiatives
- 5.4 Implement Effective Communication Techniques for Quality Leadership
- 5.5 Monitor and Measure Performance Indicators for Continuous Improvement
- 5.6 Create an Action Plan for Sustaining Quality Improvements in the Workplace

4 Quality Control Techniques

5 chapters · 30 classes **45 marks**

- **1 Fundamentals of Quality Control in Medical Devices** — 6 classes
  - 1.1 Define Key Principles of Quality Control in Medical Devices
  - 1.2 Identify Standards and Regulations Impacting Quality Management
  - 1.3 Explain the Role of Quality Control in Product Lifecycle Management
  - 1.4 Explore Quality Control Tools and Techniques for Medical Devices
  - 1.5 Analyze Case Studies of Quality Control Failures in the Industry
  - 1.6 Implement a Basic Quality Control Plan for a Medical Device Project
- **2 Statistical Techniques for Quality Control** — 6 classes
  - 2.1 Understand the Importance of Statistical Techniques in Quality Control
  - 2.2 Identify Key Statistical Concepts Relevant to Medical Devices
  - 2.3 Explore Common Statistical Methods for Quality Control
  - 2.4 Apply Descriptive Statistics to Interpret Quality Data
  - 2.5 Utilize Control Charts for Monitoring Process Stability
  - 2.6 Implement Statistical Process Control (SPC) in Quality Management
- **3 Quality Control Tools and Techniques** — 6 classes
  - 3.1 Identify Key Quality Control Tools in Medical Device Management
  - 3.2 Analyze the Role of Statistical Process Control in Quality Assurance
  - 3.3 Implement Root Cause Analysis Techniques for Quality Improvement
  - 3.4 Apply Failure Mode and Effects Analysis (FMEA) in Device Production
  - 3.5 Utilize Control Charts to Monitor Manufacturing Processes
  - 3.6 Develop Action Plans Based on Quality Control Data Insights
- **4 Implementing Quality Control in Medical Device Processes** — 6 classes
  - 4.1 Identify Key Quality Control Techniques in Medical Device Manufacturing
  - 4.2 Analyze Regulatory Requirements for Quality Control in Medical Devices
  - 4.3 Develop Quality Control Plans for Medical Device Processes
  - 4.4 Implement Statistical Process Control for Quality Monitoring
  - 4.5 Evaluate Quality Control Outcomes Through Root Cause Analysis
  - 4.6 Integrate Continuous Improvement Strategies into Quality Control
- **5 Continuous Improvement and Quality Control in ISO 13485** — 6 classes
  - 5.1 Identify Key Principles of Continuous Improvement in ISO 13485
  - 5.2 Analyze Quality Control Techniques Relevant to Medical Devices
  - 5.3 Implement Tools for Effective Quality Monitoring in ISO 13485
  - 5.4 Evaluate the Role of Leadership in Sustaining Quality Improvement
  - 5.5 Develop an Action Plan for Continuous Quality Enhancement
  - 5.6 Assess Real-World Applications of ISO 13485 Quality Control Practices

5 Quality Management Principles

5 chapters · 30 classes **85 marks**

- **1 Foundations of Quality Management in Medical Devices** — 6 classes
  - 1.1 Define Quality Management Principles in Medical Devices
  - 1.2 Identify Key Regulations and Standards for Quality in Medical Devices
  - 1.3 Analyze the Role of Leadership in Quality Management Systems
  - 1.4 Evaluate Risk Management Strategies in Medical Device Quality
  - 1.5 Develop a Quality Policy for Medical Device Organizations
  - 1.6 Implement Continuous Improvement Practices in Quality Management
- **2 ISO 13485 Standards: Structure and Requirements** — 6 classes
  - 2.1 Understand the Structure of ISO 13485 Standards
  - 2.2 Identify Key Quality Management Principles in ISO 13485
  - 2.3 Explore the Requirements for Document Control in ISO 13485
  - 2.4 Assess the Importance of Risk Management in ISO 13485
  - 2.5 Evaluate Internal Audit Processes for ISO 13485 Compliance
  - 2.6 Apply ISO 13485 Standards to Develop Quality Objectives
- **3 Risk Management in Quality Management Systems** — 6 classes
  - 3.1 Identify Key Risks in Medical Device Processes
  - 3.2 Assess the Impact of Risks on Quality Management
  - 3.3 Implement Risk Control Measures in QMS
  - 3.4 Evaluate the Effectiveness of Risk Management Strategies
  - 3.5 Document Risk Management Activities for Compliance
  - 3.6 Integrate Risk Management into Continuous Improvement
- **4 Leadership and Continual Improvement in QMS** — 6 classes
  - 4.1 Define Leadership Roles in Quality Management Systems
  - 4.2 Explore the Impact of Leadership on QMS Performance
  - 4.3 Identify Key Principles of Continual Improvement
  - 4.4 Analyze Case Studies of Effective Leadership in QMS
  - 4.5 Develop Action Plans for Leadership-driven Improvements
  - 4.6 Evaluate Strategies for Sustaining Continuous Improvement
- **5 Auditing and Compliance for Medical Devices QMS** — 6 classes
  - 5.1 Understand the Role of Auditing in QMS for Medical Devices
  - 5.2 Identify Key Compliance Requirements for ISO 13485
  - 5.3 Analyze Common Audit Findings in Medical Device Quality Management
  - 5.4 Develop Effective Audit Checklists for QMS Compliance
  - 5.5 Conduct Mock Audits to Practice Compliance Evaluation
  - 5.6 Create Action Plans for Addressing Audit Nonconformities

6 Regulatory Compliance and Risk Management

5 chapters · 30 classes **85 marks**

• 1 Understanding Regulatory Frameworks for Medical Devices — 6 classes

- › 1.1 Identify Key Regulatory Bodies for Medical Devices
- › 1.2 Analyze the Role of ISO 13485 in Healthcare Compliance
- › 1.3 Explore the Essential Regulatory Frameworks in the UK
- › 1.4 Examine the Impact of Regulatory Compliance on Product Lifecycle
- › 1.5 Assess Risk Management Strategies within Medical Device Regulations
- › 1.6 Develop an Action Plan for Ensuring Regulatory Compliance

• 2 ISO 13485 Essentials: Quality Management Systems in Healthcare — 6 classes

- › 2.1 Identify Key Principles of ISO 13485
- › 2.2 Understand the Structure of Quality Management Systems
- › 2.3 Explore Regulatory Requirements for Medical Devices
- › 2.4 Analyze Risk Management Processes in Healthcare
- › 2.5 Implement Quality Management Practices in a Healthcare Setting
- › 2.6 Evaluate Compliance and Continuous Improvement Strategies

• 3 Risk Management Principles in Medical Device Development — 6 classes

- › 3.1 Identify Key Risk Management Concepts in Medical Device Development
- › 3.2 Analyze Regulatory Requirements for Risk Management in ISO 13485
- › 3.3 Evaluate Risk Assessment Techniques for Medical Devices
- › 3.4 Implement Risk Control Measures Throughout the Product Lifecycle
- › 3.5 Develop a Risk Management Plan for New Medical Device Projects
- › 3.6 Review Case Studies on Effective Risk Management in Medical Devices

• 4 Implementing Risk Management Processes per ISO 14971 — 6 classes

- › 4.1 Define Key Concepts and Terminology in ISO 14971
- › 4.2 Identify Steps of the Risk Management Process in Medical Devices
- › 4.3 Apply Risk Assessment Techniques to Medical Device Scenarios
- › 4.4 Develop a Risk Management Plan Aligned with ISO 14971
- › 4.5 Implement Risk Control Measures and Evaluate Their Effectiveness
- › 4.6 Document and Review the Risk Management Process for Compliance

• 5 Auditing and Continuous Improvement in Regulatory Compliance — 6 classes

- › 5.1 Understand the Importance of Auditing in ISO 13485 Compliance
- › 5.2 Identify Key Regulatory Requirements for Medical Device Audits
- › 5.3 Learn Techniques for Conducting Effective Compliance Audits
- › 5.4 Analyze Audit Findings for Continuous Improvement Opportunities
- › 5.5 Develop an Action Plan Based on Audit Results
- › 5.6 Implement a Cycle of Continuous Improvement in Quality Management