LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 14971 — Risk Management for Medical Devices

ISO Certification Programme

LAPT — London Academy of Professional Training

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Reference HL-EQP-14971 • ISO Health

UKPRN 10067351 • Registered in England and Wales, company 4984798

6	40	276	430	60%	Lifetime
SUBJECTS	CHAPTERS	CLASSES	TOTAL MARKS	PASS MARK	VALIDITY

AT A GLANCE

REFERENCE	**HL-EQP-14971**
AWARD	**Certificate**
ASSESSMENT	**430 marks — 258 to pass (60%)**
PREREQUISITES	**None**
VALIDITY	**Lifetime**
AWARDING BODY	**LAPT — London Academy of Professional Training**

CURRICULUM

1 ISO 14971 Framework

10 chapters · 60 classes **85 marks**

- **1 Understanding ISO 14971: Framework and Principles** — 6 classes
  - 1.1 Explore the Fundamentals of ISO 14971 Framework
  - 1.2 Identify Key Principles of Risk Management in Medical Devices
  - 1.3 Analyze the Scope and Applicability of ISO 14971
  - 1.4 Discuss the Role of Risk Management in Medical Device Lifecycle
  - 1.5 Review the Risk Assessment Process as per ISO 14971
  - 1.6 Apply ISO 14971 Principles to a Case Study in Medical Device Development
- **1 Understanding ISO 14971: Core Principles and Objectives** — 6 classes
  - 1.1 Define Core Principles of ISO 14971
  - 1.2 Identify Objectives of Risk Management in Medical Devices
  - 1.3 Explore the Risk Management Process Stages
  - 1.4 Analyze the Role of Stakeholders in Risk Management
  - 1.5 Assess Risk Acceptance Criteria and Guidelines
  - 1.6 Apply ISO 14971 Framework to Real-World Scenarios
- **2 Risk Management Process: Identification and Assessment** — 6 classes
  - 2.1 Define Key Concepts of Risk Management in ISO 14971
  - 2.2 Identify the Steps in the Risk Management Process
  - 2.3 Explore Common Sources of Risks in Medical Devices
  - 2.4 Conduct a Preliminary Hazard Analysis for Medical Devices
  - 2.5 Assess Risks Using Qualitative and Quantitative Methods
  - 2.6 Document and Communicate Risk Assessment Results Effectively
- **2 Risk Management Process: Identifying and Evaluating Risks** — 6 classes
  - 2.1 Understand the Basics of Risk Management in ISO 14971
  - 2.2 Identify Potential Hazards in Medical Devices
  - 2.3 Assess the Severity of Risks Associated with Identified Hazards
  - 2.4 Evaluate the Likelihood of Risk Occurrence
  - 2.5 Develop Risk Evaluation Criteria for Medical Devices
  - 2.6 Implement a Risk Assessment Matrix for Decision Making
- **3 Risk Control Measures and Their Implementation** — 6 classes
  - 3.1 Identify and Analyze Risk Control Measures in ISO 14971
  - 3.2 Evaluate Effectiveness of Proposed Risk Control Measures
  - 3.3 Develop Implementation Plans for Risk Control Measures
  - 3.4 Assign Responsibilities for Risk Control Implementation
  - 3.5 Monitor and Review Implemented Risk Control Measures
  - 3.6 Communicate Risk Control Measures to Stakeholders
- **3 Risk Control Measures: Implementation and Assessment** — 6 classes
  - 3.1 Identify Key Risk Control Measures for Medical Devices
  - 3.2 Develop Implementation Strategies for Risk Control Measures
  - 3.3 Evaluate Effectiveness of Risk Control Measures
  - 3.4 Document Risk Control Implementation Procedures
  - 3.5 Monitor and Review Risk Control Measures Post-Implementation
  - 3.6 Communicate Risk Control Effectiveness to Stakeholders
- **4 Post-Market Surveillance and Risk Management Updates** — 6 classes
  - 4.1 Analyze Post-Market Surveillance Data for Risk Assessment
  - 4.2 Identify Key Metrics for Effective Risk Management Updates
  - 4.3 Evaluate Reporting Requirements Under ISO 14971
  - 4.4 Implement Continuous Risk Management Processes
  - 4.5 Develop Action Plans Based on Surveillance Outcomes
  - 4.6 Communicate Risk Management Updates to Stakeholders
- **4 Post-Market Surveillance and Risk Management Updates** — 6 classes
  - 4.1 Analyze Post-Market Surveillance Data for Risk Identification
  - 4.2 Evaluate Risk Management Processes in Post-Market Surveillance
  - 4.3 Integrate Feedback Loops into Risk Management Updates
  - 4.4 Review Regulatory Requirements for Post-Market Risk Management
  - 4.5 Develop Action Plans Based on Post-Market Surveillance Findings
  - 4.6 Communicate Risk Management Updates to Stakeholders Effectively
- **5 Documentation and Quality Assurance in Risk Management** — 6 classes
  - 5.1 Identify Key Documentation Requirements in ISO 14971
  - 5.2 Develop a Risk Management Plan as per ISO 14971
  - 5.3 Implement Effective Quality Assurance Processes in Risk Management
  - 5.4 Create Comprehensive Risk Assessment Records
  - 5.5 Review and Evaluate Documentation for Compliance with ISO 14971
  - 5.6 Use Documentation to Enhance Risk Communication Strategies
- **5 Leadership in Risk Management: Cultivating a Safety Culture** — 6 classes
  - 5.1 Define Safety Culture in the Context of ISO 14971
  - 5.2 Identify Key Leadership Responsibilities in Risk Management
  - 5.3 Develop Strategies for Fostering a Safety-Oriented Environment
  - 5.4 Assess the Current Safety Culture within Your Organization
  - 5.5 Implement Leadership Practices that Promote Risk Management
  - 5.6 Evaluate the Impact of Leadership on Safety Culture and Risk Outcomes

2 Mitigation Strategies

5 chapters · 30 classes **85 marks**

- **1 Understanding Risk in Medical Devices: Key Concepts and Definitions** — 6 classes
  - 1.1 Define Key Risk Concepts in Medical Devices
  - 1.2 Explain the Importance of Risk Management in Healthcare
  - 1.3 Identify Types of Risks Associated with Medical Devices
  - 1.4 Analyze Risk Assessment Methodologies in Medical Device Context
  - 1.5 Explore Common Risk Mitigation Strategies for Medical Devices
  - 1.6 Apply Risk Management Principles to Case Studies in Medical Devices
- **2 Identifying Risks: Techniques and Tools for Medical Devices** — 6 classes
  - 2.1 Define and Categorize Risks in Medical Devices
  - 2.2 Apply Brainstorming Techniques for Risk Identification
  - 2.3 Utilize Failure Mode and Effects Analysis (FMEA)
  - 2.4 Implement Hazard Analysis Using the Preliminary Hazard Analysis (PHA) Method
  - 2.5 Conduct Interviews and Surveys for Risk Assessment
  - 2.6 Prioritize Identified Risks for Mitigation Strategies
- **3 Risk Evaluation: Assessing Severity and Likelihood** — 6 classes
  - 3.1 Define and Differentiate Severity and Likelihood in Risk Evaluation
  - 3.2 Identify Risk Assessment Methods for Medical Devices
  - 3.3 Analyze Real-World Examples of Risk Severity in Medical Devices
  - 3.4 Evaluate Likelihood: Quantitative vs Qualitative Approaches
  - 3.5 Apply a Risk Matrix to Assess Severity and Likelihood Combinations
  - 3.6 Develop Recommended Mitigation Strategies Based on Risk Evaluation Outcomes
- **4 Mitigation Strategies: Approaches and Best Practices** — 6 classes
  - 4.1 Identify Common Risks in Medical Devices
  - 4.2 Analyze Mitigation Strategies: Principles and Approaches
  - 4.3 Evaluate Regulatory Requirements for Risk Mitigation
  - 4.4 Develop a Risk Mitigation Plan for a Case Study
  - 4.5 Implement Best Practices in Risk Communication
  - 4.6 Review and Revise Mitigation Strategies Based on Feedback
- **5 Monitoring and Reviewing Mitigation Effectiveness** — 6 classes
  - 5.1 Assess Current Mitigation Strategies Effectiveness
  - 5.2 Identify Key Performance Indicators for Monitoring
  - 5.3 Implement Risk Monitoring Tools and Techniques
  - 5.4 Analyze Data for Mitigation Effectiveness Review
  - 5.5 Engage Stakeholders in Review Process
  - 5.6 Develop Continuous Improvement Plans Based on Findings

3 Practical Application of Risk Management

10 chapters · 60 classes **45 marks**

- **1 Understanding ISO 14971: Framework and Principles** — 6 classes
  - 1.1 Define ISO 14971: Overview and Objectives
  - 1.2 Identify Key Terms and Concepts in Risk Management
  - 1.3 Explore the Structure of ISO 14971: Sections and Requirements
  - 1.4 Analyze the Risk Management Process: Steps and Activities
  - 1.5 Discuss Responsibilities and Roles in Risk Management Teams
  - 1.6 Apply ISO 14971 Principles to a Case Study in Medical Devices
- **1 Understanding ISO 14971: Principles of Risk Management in Medical Devices** — 6 classes
  - 1.1 Identify Key Principles of ISO 14971
  - 1.2 Analyze the Risk Management Process for Medical Devices
  - 1.3 Evaluate Risk Assessment Techniques in Compliance with ISO 14971
  - 1.4 Implement Risk Control Measures for Medical Devices
  - 1.5 Documenting Risk Management Activities Effectively
  - 1.6 Review Real-Life Case Studies of ISO 14971 Application
- **2 Identifying Risks in Medical Device Development** — 6 classes
  - 2.1 Define Risk: Understanding Key Concepts in Medical Devices
  - 2.2 Identify Sources of Risk: Analyzing Medical Device Features
  - 2.3 Classify Risks: Categorizing Issues in Device Development
  - 2.4 Assess Impact: Evaluating Risks in Medical Device Usage
  - 2.5 Engage Stakeholders: Collaborating to Identify Risks
  - 2.6 Document Findings: Creating a Comprehensive Risk Register
- **2 Identifying and Analyzing Risks: Techniques and Tools** — 6 classes
  - 2.1 Define Risk Management Concepts in Medical Devices
  - 2.2 Identify Common Risks Associated with Medical Devices
  - 2.3 Utilize Failure Mode and Effects Analysis (FMEA) for Risk Identification
  - 2.4 Apply the Hazard Analysis Process to Medical Devices
  - 2.5 Analyze Risk Data Using Quantitative and Qualitative Methods
  - 2.6 Develop a Risk Management Plan Based on Identified Risks
- **3 Risk Analysis Techniques for Medical Devices** — 6 classes
  - 3.1 Identify Common Risk Analysis Techniques for Medical Devices
  - 3.2 Apply Failure Mode and Effects Analysis (FMEA) to Device Design
  - 3.3 Conduct a Hazard Analysis to Evaluate Device Risks
  - 3.4 Utilize the Fault Tree Analysis (FTA) Method for Risk Assessment
  - 3.5 Compare and Contrast Qualitative and Quantitative Risk Analysis Approaches
  - 3.6 Develop a Risk Management Plan Based on Analysis Findings
- **3 Risk Evaluation and Acceptance Criteria in Medical Device Development** — 6 classes
  - 3.1 Identify Key Risks in Medical Device Development
  - 3.2 Define Acceptance Criteria for Risk Evaluation
  - 3.3 Analyze Risk Factors Using ISO 14971 Guidelines
  - 3.4 Prioritize Risks Based on Impact and Likelihood
  - 3.5 Develop Risk Control Measures and Their Evaluation
  - 3.6 Communicate Risk Evaluation Outcomes to Stakeholders
- **4 Risk Control Measures and Implementation** — 6 classes
  - 4.1 Identify and Assess Risk Control Measures
  - 4.2 Evaluate the Effectiveness of Risk Control Strategies
  - 4.3 Prioritize Risk Control Measures for Implementation
  - 4.4 Develop an Action Plan for Risk Mitigation
  - 4.5 Implement Risk Control Measures in Medical Devices
  - 4.6 Monitor and Review the Impact of Risk Controls
- **4 Implementing Risk Control Measures: Strategies and Best Practices** — 6 classes
  - 4.1 Identify Potential Risks in Medical Devices
  - 4.2 Evaluate the Impact of Risks on Patient Safety
  - 4.3 Develop Effective Risk Control Measures
  - 4.4 Implementing Risk Control Strategies in Design
  - 4.5 Monitor and Review Risk Control Effectiveness
  - 4.6 Communicate Risk Management Practices to Stakeholders
- **5 Continuous Risk Management: Monitoring and Review** — 6 classes
  - 5.1 Identify Key Monitoring Objectives in Risk Management
  - 5.2 Establish Criteria for Reviewing Risk Management Processes
  - 5.3 Implement Effective Continuous Monitoring Techniques
  - 5.4 Analyze Data Trends to Assess Risk Management Efficacy
  - 5.5 Document Findings and Recommendations for Improvement
  - 5.6 Communicate Risk Management Review Outcomes to Stakeholders
- **5 Monitoring and Reviewing Risk Management Activities Over Product Lifecycle** — 6 classes
  - 5.1 Analyze Risk Management Activities in Product Lifecycle
  - 5.2 Identify Key Performance Indicators for Risk Monitoring
  - 5.3 Implement Regular Review Processes for Risk Management
  - 5.4 Evaluate Effectiveness of Risk Mitigation Strategies
  - 5.5 Document Findings and Insights on Risk Management
  - 5.6 Develop Action Plans for Continuous Risk Improvement

4 Regulatory Affairs in Medical Devices

5 chapters · 36 classes **45 marks**

• 1 Understanding the Regulatory Landscape for Medical Devices in the UK — 6 classes

- › 1.1 Identify Key Regulatory Bodies for Medical Devices in the UK
- › 1.2 Explain the Importance of ISO Standards in Medical Device Regulation
- › 1.3 Describe the General Regulatory Framework for Medical Devices in the UK
- › 1.4 Analyze the UKCA Marking Requirements for Medical Devices
- › 1.5 Evaluate Risk Management Principles Under ISO 14971 for Compliance
- › 1.6 Develop a Compliance Strategy for Medical Devices in the UK Regulatory Environment

• 2 Introduction to ISO 14971 and Its Importance in Risk Management — 6 classes

- › 2.1 Define ISO 14971 and Its Key Concepts
- › 2.2 Explore the Historical Context of ISO 14971 in Medical Device Regulation
- › 2.3 Identify the Core Principles of Risk Management in Medical Devices
- › 2.4 Analyze the Benefits of Implementing ISO 14971 in Device Development
- › 2.5 Examine Real-World Case Studies of ISO 14971 Applications
- › 2.6 Develop a Risk Management Plan Based on ISO 14971 Guidelines

• 3 Identifying and Analyzing Risks in Medical Device Development — 6 classes

- › 3.1 Define Risk Management Concepts in Medical Devices
- › 3.2 Identify Potential Hazards in Medical Device Development
- › 3.3 Analyze Risk Factors Using the ISO 14971 Framework
- › 3.4 Evaluate the Severity and Probability of Identified Risks
- › 3.5 Develop Risk Control Measures for Mitigating Identified Risks
- › 3.6 Document and Communicate Risk Management Findings Effectively

• 4 Implementing Risk Control Measures and Evaluation of Residual Risks — 6 classes

- › 4.1 Identify Risk Control Measures for Medical Devices
- › 4.2 Assess the Effectiveness of Risk Control Measures
- › 4.3 Determine Acceptable Residual Risk Levels
- › 4.4 Conduct a Risk-benefit Analysis for Medical Devices
- › 4.5 Document and Communicate Risk Control Outcomes
- › 4.6 Review and Update Risk Management Plans

• 5 Risk Management Documentation and Regulatory Compliance — 12 classes

- › 5.1 Identify Key Components of Risk Management Documentation
- › 5.1 Understand ISO 14971: Key Principles of Risk Management for Medical Devices
- › 5.2 Explain the Principles of ISO 14971 in Regulatory Context
- › 5.2 Identify Regulatory Requirements: Aligning ISO 14971 with Compliance Standards
- › 5.3 Analyze Risk Assessment Processes for Medical Devices
- › 5.3 Develop Risk Management Plans: Structuring Documentation for Medical Devices
- › 5.4 Develop Risk Management Plans Aligned with Regulatory Standards
- › 5.4 Conduct Risk Assessments: Techniques for Effective Hazard Identification
- › 5.5 Create a Framework for Ongoing Risk Monitoring and Reporting
- › 5.5 Create Risk Control Measures: Strategies for Mitigating Identified Risks
- › 5.6 Evaluate Compliance Strategies for Effective Documentation Management
- › 5.6 Review and Update Risk Documentation: Ensuring Ongoing Regulatory Compliance

5 Risk Assessment Principles

5 chapters · 30 classes **125 marks**

• 1 Foundations of Risk Management in Medical Devices — 6 classes

- › 1.1 Define Risk Management Concepts in Medical Devices
- › 1.2 Identify Key Components of ISO 14971 Framework
- › 1.3 Analyze the Importance of Risk Assessment in Device Safety
- › 1.4 Evaluate Common Risk Management Strategies
- › 1.5 Apply Risk Assessment Tools to Real-World Scenarios
- › 1.6 Develop a Risk Assessment Plan for a Hypothetical Device

• 2 Identifying Hazards and Risk Analysis Techniques — 6 classes

- › 2.1 Define Medical Device Hazards and their Impact
- › 2.2 Explore Risk Analysis Techniques in Detail
- › 2.3 Apply the Preliminary Hazard Analysis Method
- › 2.4 Conduct a Failure Modes and Effects Analysis (FMEA)
- › 2.5 Utilize the Fault Tree Analysis (FTA) Approach
- › 2.6 Integrate Risk Assessment Findings into Device Design

• 3 Risk Evaluation and Acceptance Criteria — 6 classes

- › 3.1 Define Risk Evaluation and Its Importance in Medical Devices
- › 3.2 Identify Key Concepts of Acceptance Criteria in Risk Management
- › 3.3 Analyze Risk Assessment Methods for Effective Decision-Making
- › 3.4 Develop Criteria for Acceptable Risk Levels in Medical Devices
- › 3.5 Apply Real-World Examples to Assess Risks in Medical Device Scenarios
- › 3.6 Create a Risk Evaluation Report Using ISO 14971 Standards

• 4 Risk Control Strategies and Implementation — 6 classes

- › 4.1 Identify Key Risk Control Strategies for Medical Devices
- › 4.2 Evaluate the Effectiveness of Risk Control Measures
- › 4.3 Apply Hierarchy of Controls in Risk Management
- › 4.4 Implement Risk Control Strategies in Practice
- › 4.5 Monitor and Review Risk Control Implementations
- › 4.6 Document Risk Control Processes for Compliance

• 5 Monitoring and Review of Risk Management Processes — 6 classes

- › 5.1 Define Key Terms in Risk Management Monitoring
- › 5.2 Identify Objectives for Risk Management Review Processes
- › 5.3 Explore Methods for Collecting Risk Data and Feedback
- › 5.4 Analyze Risk Review Outcomes and Identify Trends
- › 5.5 Develop Action Plans for Addressing Identified Risks
- › 5.6 Implement Continuous Improvement Practices in Risk Management

6 Team Leadership and Management

5 chapters · 60 classes **45 marks**

• 1 Understanding Leadership Roles in ISO Risk Management for Medical Devices — 12 classes

- 1.1 Identify Key Leadership Roles in ISO 14971 Risk Management
- 1.1 Explore the Fundamentals of Leadership in ISO 14971
- 1.2 Analyze Responsibilities of Team Members in Risk Assessment
- 1.2 Identify Key Leadership Roles Within ISO Risk Management Framework
- 1.3 Evaluate Leadership Styles for Effective Risk Management
- 1.3 Analyze the Responsibilities of Leaders in Medical Device Risk Management
- 1.4 Develop Communication Strategies for Risk Management Teams
- 1.4 Discuss Effective Communication Strategies for Leadership in Risk Management
- 1.5 Implement Decision-Making Processes in Risk Management
- 1.5 Evaluate Leadership Decision-Making Processes in ISO 14971 Compliance
- 1.6 Assess Team Performance in Compliance with ISO 14971 Standards
- 1.6 Apply Leadership Principles to Real-World ISO Risk Management Scenarios

• 2 Developing High-Performing Teams in a Risk Management Environment — 12 classes

- 2.1 Identify Key Roles and Responsibilities in Risk Management Teams
- 2.1 Understand the Fundamentals of Risk Management in Medical Devices
- 2.2 Establish Effective Communication Strategies for Team Collaboration
- 2.2 Identify Key Roles and Responsibilities in a High-Performing Team
- 2.3 Foster a Culture of Accountability and Ownership in Teams
- 2.3 Foster Effective Communication Strategies for Team Collaboration
- 2.4 Implement Conflict Resolution Techniques in High-Stakes Environments
- 2.4 Implement Risk Assessment Tools and Techniques in Team Settings
- 2.5 Measure Team Performance Metrics in Risk Management Processes
- 2.5 Cultivate a Culture of Continuous Improvement and Safety
- 2.6 Develop Action Plans for Continuous Improvement in Team Dynamics
- 2.6 Develop Action Plans for Managing Risks in Team Projects

• 3 Effective Communication Strategies for Risk Management Leadership — 12 classes

- 3.1 Identify Key Stakeholders in Risk Management
- 3.1 Identify Key Communication Barriers in Risk Management
- 3.2 Develop Clear Communication Channels for Team Collaboration
- 3.2 Develop Active Listening Skills for Team Leaders
- 3.3 Utilize Active Listening Techniques in Leadership
- 3.3 Craft Clear and Concise Risk Management Messages
- 3.4 Craft Effective Risk Communication Messages
- 3.4 Utilize Visual Aids to Enhance Risk Communication
- 3.5 Foster a Culture of Openness and Feedback
- 3.5 Foster Open Dialogue and Feedback Mechanisms
- 3.6 Evaluate the Impact of Communication on Risk Management Outcomes
- 3.6 Implement Collaborative Strategies for Effective Team Engagement

• 4 Navigating Challenges and Conflict in Medical Device Risk Management — 12 classes

- 4.1 Identify Common Challenges in Medical Device Risk Management
- 4.1 Identify Common Challenges in Medical Device Risk Management
- 4.2 Analyze the Impact of Conflicts on Team Dynamics
- 4.2 Analyze Sources of Conflict within Risk Management Teams
- 4.3 Develop Effective Communication Strategies for Risk Management
- 4.3 Develop Effective Communication Strategies for Team Leadership
- 4.4 Implement Conflict Resolution Techniques in Teams
- 4.4 Apply Conflict Resolution Techniques in Risk Management Scenarios
- 4.5 Foster a Collaborative Team Environment for Decision-Making
- 4.5 Create Action Plans to Mitigate Risks and Resolve Disputes
- 4.6 Evaluate Real-World Case Studies of Conflict in Risk Management
- 4.6 Evaluate Team Dynamics and Foster a Collaborative Environment

• 5 Driving Continuous Improvement and Innovation in Risk Management Practices — 12 classes

- 5.1 Assess Current Risk Management Practices
- 5.1 Identify Key Risks and Opportunities in Medical Device Management
- 5.2 Identify Opportunities for Improvement
- 5.2 Analyze Current Risk Management Practices for Improvement
- 5.3 Develop a Culture of Innovation in Teams
- 5.3 Implement Strategies for Fostering Innovation in Risk Management
- 5.4 Implement Iterative Feedback Processes
- 5.4 Engage Leadership in Cultivating a Culture of Continuous Improvement
- 5.5 Evaluate the Impact of Changes on Risk Management
- 5.5 Develop Action Plans Based on Risk Assessment Findings
- 5.6 Foster Collaboration for Continuous Improvement
- 5.6 Evaluate the Effectiveness of Innovations in Risk Management