

LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 14971RSK — Medical Device Risk Management

ISO Certification Programme



LAPT — London Academy of Professional Training

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Reference SSR-RSK-14971RSK • ISO Security Safety & Risk

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AT A GLANCE

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

CURRICULUM

1

Developing Risk Management Plans

5 chapters · 30 classes 65 marks

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

› 1.1 Define Key Concepts in Medical Device Risk Management

› 1.2 Identify Regulatory Standards Guiding Risk Management

› 1.3 Analyze Common Risks Associated with Medical Devices

› 1.4 Develop a Risk Assessment Framework for Medical Devices

› 1.5 Formulate Risk Control Strategies and Mitigation Plans

› 1.6 Evaluate the Effectiveness of Risk Management Plans in Practice

• 2 Identifying Hazards and Assessing Risks — 6 classes

› 2.1 Define Key Terms in Hazard Identification

› 2.2 Explore Common Types of Hazards in Medical Devices

› 2.3 Examine Regulatory Requirements for Risk Management

› 2.4 Identify Hazards Through Brainstorming Techniques

› 2.5 Assess Risks Using Qualitative Methods

› 2.6 Create a Risk Assessment Template for Your Device

• 3 Developing Risk Management Plans: Framework and Requirements — 6 classes

› 3.1 Define Key Concepts in Risk Management

› 3.2 Identify Stakeholders and Their Roles in Risk Management

› 3.3 Outline the Steps in Developing a Risk Management Plan

› 3.4 Analyze Risk Management Frameworks Relevant to ISO 14971

› 3.5 Develop Risk Assessment Techniques and Tools

› 3.6 Review and Evaluate Risk Management Plans for Compliance

• 4 Implementing Risk Control Measures — 6 classes

› 4.1 Identify Key Risk Control Measures for Medical Devices

› 4.2 Assess the Effectiveness of Proposed Risk Control Measures

› 4.3 Develop a Risk Control Implementation Plan

› 4.4 Integrate Risk Control Measures into Product Development Lifecycle

› 4.5 Monitor and Review Risk Control Outcomes

› 4.6 Communicate Risk Control Strategies to Stakeholders

• 5 Monitoring and Reviewing Risk Management Processes — 6 classes

› 5.1 Identify Key Metrics for Risk Management Monitoring

› 5.2 Establish a Framework for Regular Risk Reviews

› 5.3 Develop Techniques for Effective Risk Data Collection

› 5.4 Analyze Trends and Patterns in Risk Management Data

› 5.5 Integrate Stakeholder Feedback into Risk Assessment Processes

› 5.6 Create a Comprehensive Risk Management Review Report

• 1 Fundamental Concepts of Risk Management in Medical Devices

— 6 classes

- › 1.1 Define Key Terms in Medical Device Risk Management
- › 1.2 Identify Components of Risk Assessment Process
- › 1.3 Analyze Types of Risks Associated with Medical Devices
- › 1.4 Explore Risk Mitigation Strategies for Medical Devices
- › 1.5 Evaluate Risk Management Frameworks for Compliance
- › 1.6 Apply Risk Management Principles to a Case Study

• 2 Identifying and Analyzing Risks in Medical Devices — 6 classes

- › 2.1 Define Key Terminology in Medical Device Risk Management
- › 2.2 Identify Potential Hazards in Medical Devices
- › 2.3 Analyze Risk Assessment Methods for Medical Devices
- › 2.4 Evaluate the Impact of Risks on Patient Safety
- › 2.5 Prioritize Risks Using a Risk Matrix Framework
- › 2.6 Develop Action Plans for Mitigating Identified Risks

• 3 Implementing Risk Controls and Mitigation Strategies — 6 classes

- › 3.1 Identify Risk Control Measures for Medical Devices
- › 3.2 Evaluate Effectiveness of Risk Mitigation Strategies
- › 3.3 Develop a Risk Control Implementation Plan
- › 3.4 Communicate Risk Control Strategies to Stakeholders
- › 3.5 Monitor and Review the Impact of Risk Controls
- › 3.6 Document Risk Management Activities and Outcomes

• 4 Monitoring and Reviewing Risk Management Processes — 6 classes

classes

- › 4.1 Identify Key Indicators for Risk Management Monitoring
- › 4.2 Establish a Framework for Reviewing Risk Management Processes
- › 4.3 Implement Continuous Monitoring Techniques for Risks
- › 4.4 Analyze Data Trends to Enhance Risk Management
- › 4.5 Facilitate Stakeholder Engagement in Risk Review Sessions
- › 4.6 Develop Action Plans Based on Risk Review Findings

• 5 Integrating Risk Management into Quality Management Systems

— 6 classes

- › 5.1 Define Key Concepts in Risk Management for Medical Devices
- › 5.2 Explain the Importance of Integrating Risk Management into Quality Systems
- › 5.3 Identify Components of a Quality Management System Related to Risk
- › 5.4 Explore ISO 14971 Guidelines for Risk Management Processes
- › 5.5 Analyze Case Studies of Effective Risk Management Integration
- › 5.6 Develop a Framework for Implementing Risk Management in Quality Systems

• 1 Understanding Risk Controls in Medical Device Management — 6 classes

classes

- › 1.1 Define Risk Controls in Medical Device Management
- › 1.2 Identify Common Risk Factors in Medical Devices
- › 1.3 Analyze the Importance of Risk Controls
- › 1.4 Explore Different Types of Risk Control Measures
- › 1.5 Evaluate the Effectiveness of Implemented Controls
- › 1.6 Integrate Risk Control Strategies into Device Processes

• 2 Identifying and Evaluating Risks in Medical Devices — 6 classes

- › 2.1 Analyze Potential Hazards in Medical Devices
- › 2.2 Identify Risk Factors Specific to Device Usage
- › 2.3 Assess the Likelihood of Risk Occurrence
- › 2.4 Evaluate Severity of Potential Risks
- › 2.5 Prioritize Risks for Effective Management
- › 2.6 Develop and Implement Risk Control Measures

• 3 Developing Effective Risk Control Measures — 6 classes

- › 3.1 Identify Key Risks in Medical Devices
- › 3.2 Analyze Risk Management Principles
- › 3.3 Develop Strategies for Risk Control
- › 3.4 Implement Risk Control Measures Effectively
- › 3.5 Evaluate the Effectiveness of Risk Controls
- › 3.6 Document and Communicate Risk Control Outcomes

• 4 Implementing and Monitoring Risk Controls — 6 classes

- › 4.1 Identify and Assess Risk Control Options
- › 4.2 Develop Effective Risk Control Plans
- › 4.3 Implementing Risk Controls in Medical Devices
- › 4.4 Train Teams on Risk Control Procedures
- › 4.5 Monitor and Evaluate the Effectiveness of Risk Controls
- › 4.6 Documenting Changes and Continuous Improvement in Risk Management

• 5 Continuous Improvement and Regulatory Compliance for Risk Management — 6 classes

- › 5.1 Evaluate Current Risk Management Practices
- › 5.2 Identify Opportunities for Risk Control Enhancement
- › 5.3 Develop a Continuous Improvement Framework
- › 5.4 Integrate Regulatory Compliance within Risk Management
- › 5.5 Monitor and Measure Risk Control Effectiveness
- › 5.6 Foster a Culture of Continuous Improvement in Risk Management

• 1 Fundamentals of ISO 14971: Understanding Risk Management

Principles — 6 classes

- › 1.1 Define Key Terms in ISO 14971 Risk Management
- › 1.2 Explore the Importance of Risk Management in Medical Devices
- › 1.3 Identify the Main Components of ISO 14971
- › 1.4 Explain the Risk Management Process Steps
- › 1.5 Assess Risk Through Hazard Identification Techniques
- › 1.6 Implement Risk Control Measures in Medical Device Development

• 2 Risk Management Process: Phases and Activities in ISO 14971 —

6 classes

- › 2.1 Define the Risk Management Process in ISO 14971
- › 2.2 Identify Key Phases of Risk Management in Medical Device Development
- › 2.3 Explore Risk Assessment Techniques within ISO 14971
- › 2.4 Conduct Risk Control Measures: Strategies and Implementation
- › 2.5 Monitor and Review Risk Management Activities Effectively
- › 2.6 Apply ISO 14971 in Real-World Medical Device Scenarios

• 3 Risk Analysis Techniques: Tools and Methods for Medical Devices —

6 classes

- › 3.1 Identify Key Risk Analysis Techniques for Medical Devices
- › 3.2 Evaluate the Efficacy of Qualitative Risk Assessment Methods
- › 3.3 Apply Quantitative Risk Analysis Tools in Case Studies
- › 3.4 Compare Benefits of Various Risk Management Frameworks
- › 3.5 Develop Risk Scenarios Using HAZOP Methodology
- › 3.6 Design an Effective Risk Management Plan for a Medical Device

• 4 Risk Evaluation and Mitigation: Strategies for Compliance —

6 classes

- › 4.1 Identify Key Components of Risk Evaluation in ISO 14971
- › 4.2 Analyze Risk Assessment Techniques for Medical Devices
- › 4.3 Evaluate Risk Acceptability Criteria within Compliance Frameworks
- › 4.4 Develop Risk Mitigation Strategies for Identified Risks
- › 4.5 Implement Effective Monitoring Practices for Risk Management
- › 4.6 Review Case Studies: Successful Compliance in Risk Mitigation

• 5 Post-Market Surveillance and Continuous Risk Management under ISO 14971 —

6 classes

- › 5.1 Identify Key Components of Post-Market Surveillance in ISO 14971
- › 5.2 Analyze the Importance of Continuous Risk Management for Medical Devices
- › 5.3 Evaluate Methods for Collecting Post-Market Data Effectively
- › 5.4 Implement Tools for Ongoing Risk Assessment in the Post-Market Phase
- › 5.5 Develop Strategies for Responding to Identified Risks Post-Market
- › 5.6 Create a Comprehensive Post-Market Surveillance Plan for Compliance

• 1 Understanding ISO 14971: Framework for Medical Device Risk Management —

6 classes

- › 1.1 Define Key Concepts of ISO 14971 in Medical Device Risk Management
- › 1.2 Identify the Principles of Risk Management According to ISO 14971
- › 1.3 Analyze the Risk Management Process Stages in ISO 14971
- › 1.4 Explore Tools and Techniques for Risk Identification in Medical Devices
- › 1.5 Evaluate Risk Control Measures as Outlined in ISO 14971
- › 1.6 Implement an Effective Risk Management Plan in Compliance with ISO 14971

• 2 Regulatory Compliance Requirements in Risk Management for Medical Devices —

6 classes

- › 2.1 Define Regulatory Compliance in Medical Device Risk Management
- › 2.2 Identify Key Regulatory Bodies and Their Roles
- › 2.3 Outline Essential Regulatory Compliance Requirements
- › 2.4 Analyze Risk Management Standards in Medical Device Regulations
- › 2.5 Assess the Impact of Non-compliance in Medical Devices
- › 2.6 Develop an Action Plan for Regulatory Compliance Auditing

• 3 Risk Assessment Processes: Identifying and Evaluating Risks —

6 classes

- › 3.1 Define Key Terms in Risk Assessment for Medical Devices
- › 3.2 Identify Common Risks Associated with Medical Devices
- › 3.3 Analyze Risk Context through Stakeholder Perspectives
- › 3.4 Evaluate Risk Severity and Probability in Medical Device Use
- › 3.5 Develop a Risk Assessment Matrix for Practical Application
- › 3.6 Document and Communicate Risk Assessment Findings Effectively

• 4 Risk Control Measures: Implementing Strategies to Mitigate Risks —

6 classes

- › 4.1 Identify Key Risk Factors in Medical Devices
- › 4.2 Assess the Impact of Identified Risks
- › 4.3 Develop Effective Risk Control Strategies
- › 4.4 Implement Risk Mitigation Measures
- › 4.5 Monitor and Review Risk Control Effectiveness
- › 4.6 Document and Communicate Risk Management Outcomes

• 5 Auditing for Compliance: Tools and Techniques for ISO 14971 —

6 classes

- › 5.1 Identify Key Auditing Principles for ISO 14971 Compliance
- › 5.2 Analyze Common Audit Tools Used in Medical Device Risk Management
- › 5.3 Develop an Effective Audit Plan for ISO 14971 Assessments
- › 5.4 Implement Techniques for Conducting Thorough Compliance Audits
- › 5.5 Evaluate Audit Findings and Their Implications on Risk Management
- › 5.6 Create a Continuous Improvement Framework Based on Audit Results

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

- › 1.1 Define Key Concepts in Medical Device Risk Management
- › 1.2 Identify Sources of Risk in Medical Devices
- › 1.3 Analyze the Risk Assessment Lifecycle
- › 1.4 Explore Risk Evaluation Techniques and Criteria
- › 1.5 Apply Risk Mitigation Strategies to Case Studies
- › 1.6 Develop a Risk Management Plan for a Medical Device

• 2 Identifying Hazards and Assessing Risks — 6 classes

- › 2.1 Recognize Common Hazards in Medical Devices
- › 2.2 Utilize Tools for Hazard Identification
- › 2.3 Analyze Potential Risks Associated with Identified Hazards
- › 2.4 Categorize Risks Based on Severity and Likelihood
- › 2.5 Develop Risk Assessment Documentation
- › 2.6 Implement Risk Control Measures and Evaluate Effectiveness

• 3 Qualitative Risk Analysis Methodologies — 6 classes

- › 3.1 Identify Key Principles of Qualitative Risk Analysis
- › 3.2 Explore Common Qualitative Risk Analysis Techniques
- › 3.3 Evaluate Risk Factors Using SWOT Analysis
- › 3.4 Conduct a Failure Mode and Effects Analysis (FMEA)
- › 3.5 Develop Risk Scenarios and Impact Assessment
- › 3.6 Implement Qualitative Risk Mitigation Strategies

• 4 Quantitative Risk Assessment Techniques — 6 classes

- › 4.1 Understand the Role of Quantitative Risk Assessment in Medical Devices
- › 4.2 Identify Key Quantitative Risk Assessment Techniques
- › 4.3 Apply Probability and Impact Analysis for Risk Evaluation
- › 4.4 Use Fault Tree Analysis to Model Failure Risks
- › 4.5 Implement Monte Carlo Simulation for Risk Calculation
- › 4.6 Integrate Findings into a Risk Mitigation Strategy

• 5 Implementing Risk Control Strategies and Monitoring — 6 classes

- › 5.1 Identify Applicable Risk Control Measures for Medical Devices
- › 5.2 Evaluate the Effectiveness of Risk Control Strategies
- › 5.3 Document Risk Control Implementation Processes
- › 5.4 Establish Monitoring Plans for Risk Control Efficacy
- › 5.5 Analyze Feedback and Incident Reports for Risk Assessment
- › 5.6 Adapt Risk Control Strategies Based on Monitoring Outcomes