

# LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

## ISO 10993 — Biological Evaluation of Medical Devices

*ISO Certification Programme*



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### LAPT — London Academy of Professional Training

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**Reference** HL-EQP-10993 • ISO Health

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AT A GLANCE

|               |                                                |
|---------------|------------------------------------------------|
| REFERENCE     | HL-EQP-10993                                   |
| AWARD         | Certificate                                    |
| ASSESSMENT    | 430 marks — 258 to pass (60%)                  |
| PREREQUISITES | None                                           |
| VALIDITY      | Lifetime                                       |
| AWARDING BODY | LAPT — London Academy of Professional Training |

CURRICULUM

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| <div><div>1</div><div>Biological Evaluation Principles</div><div>5 chapters · 30 classes 105 marks</div></div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <div><div>• 1 Fundamentals of Biological Evaluation in Medical Devices — 6 classes</div><div><div>› 1.1 Define Key Concepts in Biological Evaluation</div><div>› 1.2 Identify Regulatory Frameworks Guiding Biological Evaluation</div><div>› 1.3 Analyze Types of Biological Risks Associated with Medical Devices</div><div>› 1.4 Discuss Methods for Assessing Biological Safety</div><div>› 1.5 Evaluate Real-World Case Studies of Biological Evaluations</div><div>› 1.6 Apply Biological Evaluation Principles to New Medical Device Proposals</div></div></div> <div><div>• 2 ISO 10993 Standards Overview — 6 classes</div><div><div>› 2.1 Define ISO 10993 and Its Importance in Medical Device Safety</div><div>› 2.2 Explore the Structure of ISO 10993 Standards and Key Components</div><div>› 2.3 Identify Different Types of Biological Evaluations Required by ISO 10993</div><div>› 2.4 Explain Risk Assessment Processes in ISO 10993 Compliance</div><div>› 2.5 Analyze Case Studies of ISO 10993 Applications in Industry</div><div>› 2.6 Develop a Plan for Implementing ISO 10993 Standards in a Medical Device Project</div></div></div> <div><div>• 3 Risk Assessment and Management in Biological Evaluation — 6 classes</div><div><div>› 3.1 Identify Key Concepts in Risk Assessment for Biological Evaluation</div><div>› 3.2 Analyze the Components of Biological Risk Management Plans</div><div>› 3.3 Evaluate Methods for Hazard Identification in Medical Devices</div><div>› 3.4 Apply Risk Assessment Frameworks to Evaluate Biological Safety</div><div>› 3.5 Develop Risk Mitigation Strategies for Medical Device Biocompatibility</div><div>› 3.6 Assess the Impact of Regulatory Standards on Risk Management Practices</div></div></div> | <div><div>• 4 Testing Methods and Evaluation Techniques for Biological Safety — 6 classes</div><div><div>› 4.1 Identify Key Testing Methods for Biological Safety</div><div>› 4.2 Analyze the Importance of In Vitro Testing Techniques</div><div>› 4.3 Evaluate In Vivo Testing Procedures and Their Applications</div><div>› 4.4 Compare and Contrast Biocompatibility Testing Approaches</div><div>› 4.5 Assess the Role of Risk Management in Biological Evaluation</div><div>› 4.6 Apply Evaluation Techniques to Real-world Medical Device Scenarios</div></div></div> <div><div>• 5 Regulatory Compliance and Documentation for Biological Evaluation — 6 classes</div><div><div>› 5.1 Understand Regulatory Frameworks for Biological Evaluation</div><div>› 5.2 Identify Key Documentation Requirements for ISO 10993</div><div>› 5.3 Analyze Risk Assessment Protocols in Biological Evaluation</div><div>› 5.4 Explore Methods for Gathering Biological Safety Data</div><div>› 5.5 Review Case Studies on Compliance and Non-compliance Outcomes</div><div>› 5.6 Develop a Compliance Checklist for Biological Evaluation Documentation</div></div></div> |

**• 1 Understanding ISO 10993 Standards and Their Importance — 6**

classes

- › 1.1 Define ISO 10993 and Its Role in Medical Device Safety
- › 1.2 Explore the Key Components of ISO 10993 Standards
- › 1.3 Identify the Types of Biological Risks Assessed by ISO 10993
- › 1.4 Analyze the Importance of Biological Evaluation in Device Development
- › 1.5 Evaluate Case Studies of ISO 10993 Implementation in Medical Devices
- › 1.6 Apply ISO 10993 Guidelines to a Mock Device Evaluation

**• 2 Types of Biological Testing: In Vitro and In Vivo Approaches — 6**

classes

- › 2.1 Differentiate Between In Vitro and In Vivo Testing Approaches
- › 2.2 Identify Key Regulations Governing Biological Testing
- › 2.3 Analyze the Benefits and Limitations of In Vitro Testing
- › 2.4 Examine the Importance of In Vivo Testing in Medical Device Evaluation
- › 2.5 Evaluate Case Studies Involving In Vitro and In Vivo Methods
- › 2.6 Apply Best Practices for Choosing the Appropriate Testing Method

**• 3 Risk Assessment Methodologies in Biological Evaluations — 6**

classes

- › 3.1 Define Key Concepts in Risk Assessment for Biological Evaluations
- › 3.2 Identify Hazardous Biological Materials in Medical Devices
- › 3.3 Analyze Risk Assessment Methodologies Used in ISO 10993
- › 3.4 Evaluate the Impact of Material Composition on Biological Risk
- › 3.5 Develop a Risk Management Plan for Biological Evaluations
- › 3.6 Apply Risk Assessment Findings to Real-world Medical Device Scenarios

**• 4 Interpreting Laboratory Results and Data Analysis Techniques — 6**

classes

- › 4.1 Identify Key Laboratory Result Parameters for ISO 10993
- › 4.2 Analyze Data Trends from Biological Evaluation Tests
- › 4.3 Compare Expected and Observed Laboratory Outcomes
- › 4.4 Interpret Statistical Significance in Testing Results
- › 4.5 Evaluate the Impact of Variability in Laboratory Data
- › 4.6 Apply Analysis Techniques to Real-World Case Studies

**• 5 Regulatory Considerations and Reporting Requirements — 6**

classes

- › 5.1 Identify Key Regulatory Frameworks for ISO 10993 Compliance
- › 5.2 Analyze the Importance of Biological Evaluation in Medical Devices
- › 5.3 Outline Essential Reporting Requirements for Laboratory Test Results
- › 5.4 Evaluate Risk Assessment Strategies Under ISO 10993 Guidelines
- › 5.5 Implement Best Practices for Documentation and Reporting
- › 5.6 Apply Regulatory Considerations to Case Studies in Medical Device Testing

**• 1 Understanding ISO 10993 Standards and Their Importance — 6**

classes

- › 1.1 Explore the Fundamentals of ISO 10993 Standards
- › 1.2 Analyze the Role of Biological Evaluation in Medical Devices
- › 1.3 Identify Key Requirements for Compliance with ISO 10993
- › 1.4 Discuss the Implications of Non-Compliance in Quality Assurance
- › 1.5 Evaluate Case Studies Illustrating Successful ISO 10993 Implementation
- › 1.6 Develop a Strategic Plan for Integrating ISO 10993 into Quality Frameworks

**• 2 Biological Evaluation Frameworks and Risk Management — 6**

classes

- › 2.1 Understand the Goals of Biological Evaluation in Medical Device Quality Assurance
- › 2.2 Explore the Key Components of ISO 10993 Standards
- › 2.3 Identify Risk Management Principles in Biological Evaluations
- › 2.4 Analyze Biological Data and Its Impact on Device Safety
- › 2.5 Apply Risk Assessment Techniques for Biological Evaluation
- › 2.6 Develop a Biological Evaluation Plan Based on ISO 10993 Frameworks

**• 3 Leadership Skills in Quality Assurance Processes — 6**

- › 3.1 Identify Key Leadership Traits for Quality Assurance
- › 3.2 Analyze the Role of Communication in Quality Assurance Leadership
- › 3.3 Evaluate Decision-Making Strategies in Quality Assurance Processes
- › 3.4 Implement Team Building Techniques for Quality Assurance Teams
- › 3.5 Develop Strategies for Leading Quality Improvement Initiatives
- › 3.6 Assess the Impact of Leadership on Quality Assurance Outcomes

**• 4 Implementing Quality Assessment Strategies in Compliance — 6**

classes

- › 4.1 Identify Key Components of ISO 10993 in Quality Assessment
- › 4.2 Analyze the Role of Leadership in Implementing Compliance Strategies
- › 4.3 Develop Quality Assessment Frameworks for Medical Devices
- › 4.4 Evaluate Risk Management Approaches in Quality Assurance
- › 4.5 Design Effective Training Programs for Compliance Execution
- › 4.6 Implement Continuous Improvement Techniques in Quality Assessment

**• 5 Future Trends in Quality Assurance and ISO 10993 Adaptation — 6**

classes

- › 5.1 Analyze Future Trends Impacting Quality Assurance in Medical Devices
- › 5.2 Explore ISO 10993 Adaptation for Emerging Technologies
- › 5.3 Evaluate the Role of Leadership in Implementing ISO Standards
- › 5.4 Design Strategies for Incorporating Future Trends into Quality Practices
- › 5.5 Collaborate on Case Studies of Successful ISO 10993 Applications
- › 5.6 Develop Action Plans for Adapting Quality Assurance in Your Organization

**• 1 Understanding ISO 10993: Key Principles and Terminology** — 6 classes

- › 1.1 Define Key Terms in ISO 10993
- › 1.2 Explain the Importance of Biological Evaluation
- › 1.3 Identify the Scope and Application of ISO 10993
- › 1.4 Describe the Key Principles of Biological Safety
- › 1.5 Explore the Risk Assessment Process in ISO 10993
- › 1.6 Apply ISO 10993 Terminology to Case Studies

**• 2 Regulatory Requirements and Risk Management in ISO 10993** — 6 classes

- › 2.1 Identify Key Regulatory Requirements in ISO 10993
- › 2.2 Analyze the Role of Risk Management in Medical Device Evaluation
- › 2.3 Evaluate Biological Risks Associated with Medical Devices
- › 2.4 Apply Risk Assessment Methodologies According to ISO 10993
- › 2.5 Develop a Risk Management Plan for Medical Devices
- › 2.6 Implement Strategies for Compliance with ISO 10993 Regulations

**• 3 Testing and Evaluation Strategies for Biological Safety** — 6 classes

- › 3.1 Identify Key Tests for Biological Safety in Medical Devices
- › 3.2 Analyze the Role of Risk Assessment in ISO 10993 Compliance
- › 3.3 Compare In Vitro and In Vivo Testing Methods for Medical Devices
- › 3.4 Evaluate Test Results for Biological Reactivity and Safety
- › 3.5 Develop a Biological Evaluation Plan Based on ISO 10993 Standards
- › 3.6 Implement Post-Market Surveillance Strategies for Biological Safety

**• 4 Practical Application of ISO 10993: Case Studies** — 6 classes

- › 4.1 Analyze Case Studies of Successful ISO 10993 Implementations
- › 4.2 Identify Key Challenges in Biological Evaluations of Medical Devices
- › 4.3 Evaluate the Impact of ISO 10993 on Device Safety and Efficacy
- › 4.4 Compare Different Assessment Strategies Used in Case Studies
- › 4.5 Develop a Step-by-Step Approach to Conduct a Biological Evaluation
- › 4.6 Present Lessons Learned from Case Studies to Enhance Team Practices

**• 5 Future Trends in Biological Evaluation of Medical Devices** — 6 classes

- › 5.1 Analyze Emerging Trends in ISO 10993 Application
- › 5.2 Evaluate Impact of Technological Advancements on Biological Testing
- › 5.3 Assess Regulatory Changes Affecting Biological Evaluations
- › 5.4 Explore Innovations in Test Methods for Medical Devices
- › 5.5 Implement Best Practices for Future Biological Evaluations
- › 5.6 Predict Future Challenges in ISO 10993 Compliance

**• 1 Understanding Medical Device Regulatory Standards** — 6 classes

- › 1.1 Identify Key Regulatory Standards for Medical Devices
- › 1.2 Explore the ISO 10993 Framework for Biological Evaluation
- › 1.3 Analyze the Importance of Risk Management in Device Evaluation
- › 1.4 Examine Case Studies of ISO 10993 Compliance in Practice
- › 1.5 Develop Strategies for Implementing ISO Guidelines in Organizations
- › 1.6 Assess the Impact of Regulatory Changes on Medical Device Development

**• 2 Key Components of the ISO 10993 Standard** — 6 classes

- › 2.1 Understand the Purpose of ISO 10993 in Biological Evaluation
- › 2.2 Identify the Key Components of ISO 10993
- › 2.3 Explore the Risk Management Process in ISO 10993
- › 2.4 Examine the Roles of Biocompatibility Testing in Medical Devices
- › 2.5 Analyze the Documentation Requirements for Compliance
- › 2.6 Apply ISO 10993 Principles in Real-World Case Studies

**• 3 Risk Management in Medical Device Evaluation** — 6 classes

- › 3.1 Identify key principles of risk management in medical devices
- › 3.2 Analyze the role of ISO 14971 in establishing risk management processes
- › 3.3 Assess the types of risks associated with medical device products
- › 3.4 Evaluate risk control measures and their effectiveness
- › 3.5 Conduct a risk-benefit analysis for a specific medical device
- › 3.6 Develop a comprehensive risk management plan for a medical device project

**• 4 Regulatory Pathways for Market Approval** — 6 classes

- › 4.1 Identify the Key Regulatory Bodies Involved in Medical Device Approval
- › 4.2 Explain the Importance of Regulatory Compliance for Medical Devices
- › 4.3 Compare Pre-market and Post-market Regulatory Pathways
- › 4.4 Analyze the Steps for Navigating the CE Marking Process
- › 4.5 Evaluate the Role of Clinical Evaluation in Market Approval
- › 4.6 Apply Regulatory Knowledge to Case Studies of Medical Device Approvals

**• 5 Case Studies on ISO 10993 Implementation** — 6 classes

- › 5.1 Analyze Key Components of ISO 10993 Standards
- › 5.2 Evaluate Case Studies of Successful ISO 10993 Implementation
- › 5.3 Identify Common Challenges in ISO 10993 Compliance
- › 5.4 Develop Strategies for Effective Risk Management in ISO 10993
- › 5.5 Assess the Impact of ISO 10993 on Device Safety and Efficacy
- › 5.6 Apply ISO 10993 Principles to a Hypothetical Medical Device Scenario

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

- › 1.1 Define Key Concepts in Risk Management for Medical Devices
- › 1.2 Identify Regulatory Frameworks Influencing Risk Assessment
- › 1.3 Analyze Potential Hazards Associated with Medical Devices
- › 1.4 Evaluate Risk Control Measures in Medical Device Development
- › 1.5 Apply Risk Management Principles in Case Studies of Medical Devices
- › 1.6 Develop a Risk Management Plan for a Hypothetical Medical Device

**• 2 ISO 14971: The Standard for Risk Management** — 6 classes

- › 2.1 Understand ISO 14971: Key Concepts and Terminology
- › 2.2 Explore the Risk Management Process Framework
- › 2.3 Identify Potential Hazards in Medical Devices
- › 2.4 Evaluate Risks: Assessing Severity and Likelihood
- › 2.5 Implement Risk Control Measures and Their Effectiveness
- › 2.6 Document and Communicate Risk Management Outcomes

**• 3 Identifying Hazards and Assessing Risks** — 6 classes

- › 3.1 Define Hazard Types in Medical Devices
- › 3.2 Identify Common Risks in Medical Device Usage
- › 3.3 Conduct Preliminary Risk Assessments
- › 3.4 Analyze Risk Factors for Biological Safety
- › 3.5 Evaluate Risk Control Measures for Medical Devices
- › 3.6 Document and Communicate Risk Assessments Effectively

**• 4 Risk Control Measures and Evaluation** — 6 classes

- › 4.1 Identify Key Risk Control Measures in ISO 10993 Framework
- › 4.2 Analyze the Effectiveness of Risk Control Measures
- › 4.3 Develop a Risk Evaluation Plan for Medical Devices
- › 4.4 Implement Strategies for Mitigating Identified Risks
- › 4.5 Assess Compliance with Risk Management Regulations
- › 4.6 Review and Report Findings from Safety Assessments

**• 5 Clinical Safety Assessment and Post-Market Surveillance** — 6 classes

- › 5.1 Assess Clinical Safety Risks in Medical Devices
- › 5.2 Identify Key Regulations for Post-Market Surveillance
- › 5.3 Analyze Clinical Evidence from Post-Market Data
- › 5.4 Develop a Monitoring Plan for Device Safety
- › 5.5 Evaluate Effectiveness of Risk Management Strategies
- › 5.6 Implement Continuous Improvement in Clinical Safety Assessments