

LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 22442 — Medical Devices Utilizing Animal Tissues

ISO Certification Programme



LAPT — London Academy of Professional Training

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Reference HL-EQP-22442 • ISO Health

UKPRN 10067351 • Registered in England and Wales, company 4984798

AT A GLANCE

REFERENCE	HL-EQP-22442
AWARD	Certificate
ASSESSMENT	430 marks — 258 to pass (60%)
PREREQUISITES	None
VALIDITY	Lifetime
AWARDING BODY	LAPT — London Academy of Professional Training

CURRICULUM

1 Ethical Considerations 0 chapters45 marks	
2 Future Trends in Medical Devices 0 chapters45 marks	
3 Quality Assurance Principles 0 chapters85 marks	
4 Regulatory Frameworks 5 chapters · 30 classes105 marks	
• 1 Understanding the Basics of ISO 22442 and Animal Tissue Regulations — 6 classes › 1.1 Define ISO 22442 and Its Importance in Medical Devices › 1.2 Explore the Regulatory Framework Surrounding Animal Tissues › 1.3 Identify Key Terms and Definitions Related to ISO 22442 › 1.4 Analyze the Impact of Animal Tissue Regulations on Medical Device Design › 1.5 Evaluate Compliance Strategies for ISO 22442 Implementation › 1.6 Develop a Plan for Assessing Animal Tissue Sources in Medical Devices • 2 Key Regulatory Bodies and International Standards — 6 classes › 2.1 Identify Key Regulatory Bodies in Medical Device Standards › 2.2 Explain the Role of ISO in Regulating Medical Devices › 2.3 Analyze the Importance of Compliance with ISO 22442 › 2.4 Compare International Standards for Medical Devices › 2.5 Assess the Impact of Regulatory Changes on Animal Tissue Use › 2.6 Develop a Compliance Checklist for ISO 22442 Application • 3 Risk Management and Compliance in Medical Device Development — 6 classes › 3.1 Identify Key Risks in Medical Device Development › 3.2 Assess The Impact of Animal Tissue Regulations › 3.3 Implement Risk Management Strategies for Compliance › 3.4 Analyze Case Studies of Risk Management Failures › 3.5 Develop a Risk Management Plan for ISO 22442 Compliance › 3.6 Monitor and Review Compliance in Medical Device Production	• 4 Ethical Considerations and Guidelines for Animal Tissue Use — 6 classes › 4.1 Evaluate Ethical Principles Governing Animal Tissue Use › 4.2 Examine Regulatory Frameworks for Animal Tissue in Medical Devices › 4.3 Analyze Case Studies on Ethical Animal Tissue Usage › 4.4 Identify Best Practices in Animal Tissue Sourcing › 4.5 Develop Guidelines for Compliance with ISO 22442 › 4.6 Formulate a Strategy for Ethical Decision-Making in Animal Tissue Use • 5 Implementing and Auditing ISO 22442 Compliance — 6 classes › 5.1 Understand ISO 22442: Key Principles and Concepts › 5.2 Identify Regulatory Requirements and Key Stakeholders › 5.3 Develop Procedures for Complying with ISO 22442 › 5.4 Conduct Internal Audits for ISO 22442 Compliance › 5.5 Analyze Audit Findings and Implement Continuous Improvement › 5.6 Prepare for External Audits: Best Practices and Strategies

• **1 Understanding Risk Management in Medical Devices** — 6 classes

- › 1.1 Define Key Terms in Risk Management for Medical Devices
- › 1.2 Identify Common Risks Associated with Animal Tissue in Medical Devices
- › 1.3 Analyze the Risk Management Process in Medical Device Development
- › 1.4 Evaluate Risk Assessment Techniques for ISO 22442 Compliance
- › 1.5 Explore Mitigation Strategies for Identified Risks in Medical Devices
- › 1.6 Apply Risk Management Best Practices to Case Studies in Medical Device Scenarios

• **2 Identifying Risks in Animal Tissue Utilization** — 6 classes

- › 2.1 Analyze Regulatory Frameworks for Animal Tissue Use
- › 2.2 Identify Types of Risks Associated with Animal Tissues
- › 2.3 Assess Biological Hazards in Animal Tissue Utilization
- › 2.4 Evaluate Processing and Storage Risks of Animal Tissues
- › 2.5 Develop Risk Mitigation Strategies for Animal Tissue Handling
- › 2.6 Implement a Risk Assessment Model for Animal Tissue Applications

• **3 Assessing Risks Using ISO 14971 Framework** — 6 classes

- › 3.1 Understand the ISO 14971 Framework for Risk Management
- › 3.2 Identify Key Terms and Concepts Related to Risk in Medical Devices
- › 3.3 Analyze Risk Factors Specific to Animal Tissue Medical Devices
- › 3.4 Evaluate Risk Assessment Techniques Within the ISO 14971 Framework
- › 3.5 Develop a Risk Management Plan for Medical Devices Utilizing Animal Tissues
- › 3.6 Apply Risk Evaluation Outcomes to Enhance Device Safety and Compliance

• **4 Implementing Risk Control Measures** — 6 classes

- › 4.1 Identify Key Risks Associated with Animal Tissue in Medical Devices
- › 4.2 Analyze Existing Risk Control Measures in Current Practices
- › 4.3 Develop Effective Risk Control Strategies for Animal Tissue Usage
- › 4.4 Evaluate the Effectiveness of Proposed Risk Control Measures
- › 4.5 Implement Risk Control Measures and Monitor Compliance
- › 4.6 Review and Update Risk Control Measures Based on Feedback and Findings

• **5 Monitoring and Reviewing Risk Management Processes**