

LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 17511 — In Vitro Diagnostic Medical Devices Metrological Traceability

ISO Certification Programme



LAPT — London Academy of Professional Training

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Reference HL-BIO-17511 • ISO Health

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AT A GLANCE

REFERENCE	HL-BIO-17511
AWARD	Certificate
ASSESSMENT	430 marks — 258 to pass (60%)
PREREQUISITES	None
VALIDITY	Lifetime
AWARDING BODY	LAPT — London Academy of Professional Training

CURRICULUM

1

Leadership and Change Management

5 chapters · 30 classes 45 marks

• 1 Understanding Leadership Theories in Biomedical Contexts — 6 classes

› 1.1 Explore Key Leadership Theories Relevant to Biomedical Settings

› 1.2 Analyze the Impact of Transformational Leadership in Healthcare

› 1.3 Evaluate Situational Leadership and Its Application in Medical Teams

› 1.4 Discuss the Role of Servant Leadership in Patient-Centered Care

› 1.5 Integrate Leadership Theories into Effective Change Management Strategies

› 1.6 Apply Leadership Models to Real-World Biomedical Case Studies

• 2 The Role of Change Management in ISO 17511 Implementation — 6 classes

› 2.1 Understand the Importance of Change Management in ISO 17511

› 2.2 Identify Key Stakeholders in ISO 17511 Implementation

› 2.3 Assess Organizational Readiness for Change in ISO 17511

› 2.4 Develop a Strategic Change Management Plan for ISO 17511

› 2.5 Communicate Change Effectively to Ensure Stakeholder Buy-In

› 2.6 Evaluate and Adapt Change Management Strategies Post-Implementation

• 3 Building Effective Leadership Teams in Biotechnology — 6 classes

› 3.1 Define Key Characteristics of Effective Leadership Teams in Biotechnology

› 3.2 Analyze the Role of Diversity in Leadership Team Performance

› 3.3 Assess Communication Strategies Essential for Leadership Success

› 3.4 Develop Conflict Resolution Techniques for Leadership Teams

› 3.5 Implement Decision-Making Frameworks for Biotech Leadership

› 3.6 Evaluate Team Dynamics and Continuous Improvement Strategies

• 4 Navigating Regulatory Changes and Stakeholder Engagement — 6 classes

› 4.1 Identify Key Regulatory Changes Impacting In Vitro Diagnostics

› 4.2 Analyze Stakeholder Needs and Concerns in Regulatory Contexts

› 4.3 Develop Strategies for Effective Communication with Stakeholders

› 4.4 Facilitate Stakeholder Engagement Through Collaborative Workshops

› 4.5 Implement Change Management Tactics to Address Regulatory Adaptation

› 4.6 Evaluate the Effectiveness of Stakeholder Engagement Strategies

• 5 Strategic Leadership for Sustaining Change in ISO Compliance — 6 classes

› 5.1 Assess Strategic Needs for ISO 17511 Compliance

› 5.2 Establish Leadership Role in Change Management for ISO Standards

› 5.3 Develop a Vision for Sustainable ISO Compliance

› 5.4 Create a Change Management Framework for ISO 17511 Implementation

› 5.5 Engage Stakeholders in Driving ISO Compliance Initiatives

› 5.6 Evaluate and Sustain Change for Long-term ISO Compliance Success

• 1 Fundamentals of Metrological Concepts in Healthcare — 6 classes

- › 1.1 Define Metrological Traceability in Healthcare
- › 1.2 Identify Key Metrological Concepts and Principles
- › 1.3 Examine the Role of ISO Standards in In Vitro Diagnostics
- › 1.4 Analyze the Importance of Measurement Uncertainty in Diagnostics
- › 1.5 Implement Quality Control Measures for Metrological Accuracy
- › 1.6 Apply Metrological Principles to Case Studies in Healthcare

• 2 Measurement Uncertainty and Its Role in Diagnostics — 6 classes

- › 2.1 Define Measurement Uncertainty in Diagnostics
- › 2.2 Explain the Sources of Measurement Uncertainty
- › 2.3 Describe Methods for Estimating Measurement Uncertainty
- › 2.4 Analyze the Impact of Measurement Uncertainty on Diagnostic Results
- › 2.5 Discuss Regulatory Standards for Measurement Uncertainty in IVDs
- › 2.6 Apply Measurement Uncertainty Concepts to Real-World Diagnostic Scenarios

• 3 Metrological Traceability and Its Standards — 6 classes

- › 3.1 Define Metrological Traceability in Medical Devices
- › 3.2 Explain the Importance of Metrological Traceability Standards
- › 3.3 Explore the Principles of Metrology Relevant to Diagnostics
- › 3.4 Illustrate the Relationship Between Traceability and Measurement Uncertainty
- › 3.5 Analyze Case Studies of Metrological Traceability Failures
- › 3.6 Develop a Plan for Implementing Metrological Traceability in Practice

• 4 Calibration Protocols for Diagnostic Instruments — 6 classes

- › 4.1 Identify Calibration Standards for Diagnostic Instruments
- › 4.2 Explain the Importance of Metrological Traceability
- › 4.3 Develop a Calibration Protocol for Diagnostic Devices
- › 4.4 Implement Calibration Procedures in Laboratory Settings
- › 4.5 Assess Calibration Results Against ISO 17511 Standards
- › 4.6 Review and Revise Calibration Protocols for Continuous Improvement

• 5 Quality Assurance in Metrological Practices — 6 classes

- › 5.1 Identify Key Components of Quality Assurance in Metrological Practices
- › 5.2 Analyze the Role of Standardization in Metrological Quality
- › 5.3 Discuss the Importance of Traceability in Diagnostic Testing
- › 5.4 Evaluate Metrological Practices Against ISO 17511 Standards
- › 5.5 Implement Quality Control Procedures in In Vitro Diagnostics
- › 5.6 Develop an Action Plan for Continuous Improvement in Metrological Standards

• 1 Fundamentals of Quality Assurance in Biotechnology — 6 classes

- › 1.1 Define Quality Assurance in Biotechnology
- › 1.2 Explore Regulatory Frameworks in Biotechnology
- › 1.3 Identify Key Principles of Metrological Traceability
- › 1.4 Understand the Role of ISO Standards in Quality Assurance
- › 1.5 Analyze Case Studies in Quality Assurance Practices
- › 1.6 Implement Quality Assurance Strategies in Biotechnology Projects

• 2 Understanding ISO 17511 and Metrological Traceability — 6 classes

- › 2.1 Define Key Concepts of ISO 17511 and Metrological Traceability
- › 2.2 Explore the Importance of Metrological Traceability in Diagnostics
- › 2.3 Examine the Structure and Requirements of ISO 17511
- › 2.4 Identify Stakeholders and Their Roles in Metrological Traceability
- › 2.5 Analyze Case Studies Demonstrating ISO 17511 Implementation
- › 2.6 Develop a Quality Assurance Plan Incorporating ISO 17511 Principles

• 3 Implementing Quality Management Systems in Biotech — 6 classes

- › 3.1 Identify Key Components of a Quality Management System in Biotechnology
- › 3.2 Assess Compliance with ISO 17511 Standards in Biotech Practices
- › 3.3 Develop Document Control Procedures for Quality Management
- › 3.4 Implement Risk Management Strategies in Biotech Quality Assurance
- › 3.5 Conduct Internal Audits to Evaluate Quality Management Effectiveness
- › 3.6 Design a Continuous Improvement Plan for Quality Systems in Biotech

• 4 Risk Management in Quality Assurance Processes — 6 classes

- › 4.1 Identify Key Risks in Quality Assurance Processes
- › 4.2 Analyze Risk Impact on Biotechnology Outcomes
- › 4.3 Develop Risk Mitigation Strategies for ISO Compliance
- › 4.4 Implement Risk Management Frameworks in Biotechnology
- › 4.5 Evaluate the Effectiveness of Risk Management Techniques
- › 4.6 Communicate Risk Management Findings to Stakeholders

• 5 Continuous Improvement and Auditing Practices — 6 classes

- › 5.1 Identify Key Principles of Continuous Improvement in Quality Assurance
- › 5.2 Analyze the Role of Auditing in In Vitro Diagnostic Devices
- › 5.3 Evaluate Methodologies for Effective Quality Audits
- › 5.4 Implement Best Practices for Continuous Improvement in Biotechnology
- › 5.5 Develop an Action Plan Based on Audit Findings
- › 5.6 Communicate Continuous Improvement Strategies to Stakeholders

• 1 Understanding ISO 17511: Principles and Framework — 6 classes

- › 1.1 Explore the Foundations of ISO 17511
- › 1.2 Analyze the Key Principles of Metrological Traceability
- › 1.3 Identify Regulatory Compliance Requirements for In Vitro Diagnostic Devices
- › 1.4 Evaluate the Framework of ISO 17511 Applications
- › 1.5 Assess Risks in Metrological Traceability Implementation
- › 1.6 Develop an Action Plan for Compliance with ISO 17511

• 2 Regulatory Landscape for In Vitro Diagnostic Devices — 6 classes

- › 2.1 Identify Key Regulations Impacting In Vitro Diagnostic Devices
- › 2.2 Analyze the Role of ISO 17511 in Metrological Traceability
- › 2.3 Explore the Regulatory Pathway for Device Approval in the UK
- › 2.4 Evaluate Compliance Requirements for In Vitro Diagnostic Devices
- › 2.5 Assess Risk Management Strategies in Regulatory Compliance
- › 2.6 Implement Best Practices for Maintaining Compliance in Diagnostics

• 3 Metrological Traceability in Diagnostic Testing — 6 classes

- › 3.1 Define Metrological Traceability in Diagnostic Testing
- › 3.2 Explain the Importance of Traceability in Regulatory Compliance
- › 3.3 Identify Key Standards and Guidelines Related to Metrological Traceability
- › 3.4 Evaluate the Impact of Traceability on Diagnostic Accuracy
- › 3.5 Discuss Risk Management Strategies in Ensuring Traceability
- › 3.6 Apply Metrological Traceability Principles to a Case Study

• 4 Risk Management Strategies in Regulatory Compliance — 6 classes

- › 4.1 Identify Key Risks in In Vitro Diagnostic Medical Devices
- › 4.2 Analyze Regulatory Requirements for Risk Management
- › 4.3 Develop a Risk Assessment Framework for Compliance
- › 4.4 Implement Risk Mitigation Strategies in Regulatory Processes
- › 4.5 Monitor and Review Risk Management Effectiveness
- › 4.6 Communicate Risk Management Outcomes to Stakeholders

• 5 Implementing Compliance and Risk Management Systems — 6 classes

- › 5.1 Identify Key Regulations Governing In Vitro Diagnostics
- › 5.2 Assess Risks in Diagnostic Device Development
- › 5.3 Develop a Comprehensive Compliance Framework
- › 5.4 Implement Risk Management Strategies for Medical Devices
- › 5.5 Monitor and Evaluate Compliance Effectiveness
- › 5.6 Create a Continuous Improvement Plan for Risk Management

• 1 Understanding the Landscape of Stakeholder Engagement in ISO 17511 — 6 classes

- › 1.1 Identify Key Stakeholders in ISO 17511 Implementation
- › 1.2 Analyze Stakeholder Needs and Expectations
- › 1.3 Develop Effective Communication Strategies for Stakeholder Engagement
- › 1.4 Evaluate the Impact of Stakeholder Feedback on ISO 17511 Practices
- › 1.5 Implement Collaborative Approaches for Stakeholder Involvement
- › 1.6 Assess the Effectiveness of Stakeholder Engagement in Real-World Scenarios

• 2 Identifying and Mapping Stakeholders in In Vitro Diagnostics — 6 classes

- › 2.1 Define Stakeholders in In Vitro Diagnostics
- › 2.2 Identify Key Stakeholders in the In Vitro Diagnostic Ecosystem
- › 2.3 Analyze the Roles and Responsibilities of Stakeholders
- › 2.4 Create a Stakeholder Map for In Vitro Diagnostic Projects
- › 2.5 Evaluate the Influence and Interest of Stakeholders
- › 2.6 Develop a Stakeholder Engagement Communication Plan

• 3 Effective Communication Strategies for Stakeholder Involvement — 6 classes

- › 3.1 Identify Stakeholders and Their Needs
- › 3.2 Develop Clear Communication Objectives
- › 3.3 Choose Appropriate Communication Channels
- › 3.4 Craft Tailored Messages for Diverse Stakeholders
- › 3.5 Facilitate Effective Stakeholder Meetings
- › 3.6 Evaluate Communication Impact and Adapt Strategies

• 4 Developing Stakeholder Engagement Plans for Compliance — 6 classes

- › 4.1 Identify Key Stakeholders for Metrological Traceability Compliance
- › 4.2 Analyze Stakeholder Needs and Expectations in Engagement Plans
- › 4.3 Develop Effective Communication Strategies for Stakeholder Engagement
- › 4.4 Establish Methods for Stakeholder Feedback and Collaboration
- › 4.5 Create a Comprehensive Stakeholder Engagement Timeline
- › 4.6 Evaluate and Adapt Stakeholder Engagement Plans for Continuous Improvement

• 5 Evaluating and Measuring Stakeholder Engagement Outcomes — 6 classes

- › 5.1 Define Key Stakeholder Engagement Metrics
- › 5.2 Develop Tools for Collecting Engagement Data
- › 5.3 Analyze Stakeholder Feedback for Insights
- › 5.4 Create a Framework for Evaluating Engagement Outcomes
- › 5.5 Communicate Findings to Stakeholders Effectively
- › 5.6 Implement Changes Based on Evaluation Results

• 1 Understanding Metrological Traceability in IVDs — 6 classes

- › 1.1 Define Metrological Traceability in IVDs
- › 1.2 Explore the Importance of Metrological Traceability
- › 1.3 Identify Key Principles of Measurement in IVDs
- › 1.4 Analyze the Impact of Traceability on Quality Assurance
- › 1.5 Implement Best Practices for Maintaining Traceability
- › 1.6 Evaluate Case Studies on Metrological Traceability in IVDs

• 2 ISO 17511: Key Requirements and Implementation — 6 classes

- › 2.1 Understanding the Basics of ISO 17511
- › 2.2 Identifying Key Requirements of ISO 17511
- › 2.3 Exploring Metrological Traceability in IVDs
- › 2.4 Mapping ISO 17511 Standards to Current Practices
- › 2.5 Developing an Implementation Plan for ISO 17511
- › 2.6 Evaluating Continuous Improvement Strategies Post-Implementation

• 3 Strategic Planning Framework for Continuous Improvement — 6 classes

- › 3.1 Define the Key Components of a Strategic Planning Framework
- › 3.2 Assess Current Practices for Continuous Improvement
- › 3.3 Identify Stakeholders and Their Roles in the Planning Process
- › 3.4 Develop Measurable Objectives for Improvement Initiatives
- › 3.5 Create Action Plans to Implement Strategic Improvements
- › 3.6 Evaluate and Adjust Strategies Based on Performance Metrics

• 4 Performance Metrics and Evaluation in IVDs — 6 classes

- › 4.1 Identify Key Performance Metrics for IVDs
- › 4.2 Analyze the Importance of Metrological Traceability in Evaluation
- › 4.3 Develop a Framework for Continuous Improvement in IVD Performance
- › 4.4 Implement Data Collection Methods for Performance Metrics
- › 4.5 Evaluate Performance Metrics Against Industry Standards
- › 4.6 Create an Action Plan for Enhancing IVD Performance Based on Evaluation

• 5 Cultivating a Culture of Quality and Improvement — 6 classes

- › 5.1 Define Quality Culture in Healthcare Settings
- › 5.2 Identify Key Elements of Continuous Improvement
- › 5.3 Assess Current Practices for Quality in Medical Devices
- › 5.4 Implement Strategies for Enhancing Team Collaboration
- › 5.5 Create an Action Plan for Quality Improvement Initiatives
- › 5.6 Evaluate Outcomes and Sustain a Culture of Improvement