

LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 9001B — Quality Management in Biotech Labs

ISO Certification Programme



LAPT — London Academy of Professional Training

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Reference HL-BIO-9001B • ISO Health

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AT A GLANCE

REFERENCE	HL-BIO-9001B
AWARD	Certificate
ASSESSMENT	430 marks — 258 to pass (60%)
PREREQUISITES	None
VALIDITY	Lifetime
AWARDING BODY	LAPT — London Academy of Professional Training

CURRICULUM

1

Data Analysis Techniques

5 chapters · 30 classes 65 marks

• 1 Understanding Data Types and Their Relevance in Biotech Labs

— 6 classes

› 1.1 Identify Different Data Types in Biotech Research

› 1.2 Classify Qualitative vs. Quantitative Data in Lab Settings

› 1.3 Analyze the Importance of Continuous and Discrete Data in Biotech

› 1.4 Explore Measurement Scales and Their Applications in Data Collection

› 1.5 Evaluate the Impact of Data Types on Experimental Design Choices

› 1.6 Apply Appropriate Data Analysis Techniques to Biotech Case Studies

• 2 Data Collection Methods: Designing Effective Protocols

— 6 classes

› 2.1 Identify Key Objectives for Data Collection Protocols

› 2.2 Evaluate Different Types of Data Collection Methods

› 2.3 Design a Structured Data Collection Instrument

› 2.4 Implement Sampling Strategies for Accurate Data Collection

› 2.5 Test and Validate Data Collection Protocols

› 2.6 Analyze Results and Refine Data Collection Techniques

• 3 Statistical Tools for Data Analysis in Biotechnology

— 6 classes

› 3.1 Identify Key Statistical Tools Used in Biotechnology

› 3.2 Understand Descriptive Statistics for Biotech Data

› 3.3 Apply Inferential Statistics to Biotech Scenarios

› 3.4 Utilize Hypothesis Testing in Experimental Design

› 3.5 Interpret Regression Analysis for Predictive Insights

› 3.6 Create Visual Representations of Biotech Data Analysis

• 4 Visualizing Data: Best Practices for Biotech Reports

— 6 classes

› 4.1 Understand the Importance of Data Visualization in Biotech Reporting

› 4.2 Identify Common Types of Data Visualizations Used in Biotech

› 4.3 Evaluate Best Practices for Creating Effective Graphs and Charts

› 4.4 Explore Tools and Software for Data Visualization in Biotech Labs

› 4.5 Apply Data Visualization Techniques to Real-World Biotech Scenarios

› 4.6 Review and Critique Sample Biotech Reports for Visualization Effectiveness

• 5 Interpreting Results: Making Data-Driven Decisions in Biotech

— 6 classes

› 5.1 Identify Key Metrics for Biotech Success

› 5.2 Analyze Data Trends to Guide Research Directions

› 5.3 Visualize Data Effectively for Clear Interpretation

› 5.4 Evaluate Statistical Significance in Experimental Results

› 5.5 Develop Actionable Insights from Data Analysis

› 5.6 Communicate Data-Driven Recommendations to Stakeholders

• 1 Understanding ISO 9001: The Foundation of Quality Management

— 6 classes

- › 1.1 Define ISO 9001: Exploring Key Concepts and Terminology
- › 1.2 Identify the Principles of Quality Management in ISO 9001
- › 1.3 Describe the Structure of the ISO 9001 Standard
- › 1.4 Analyze the Importance of Quality Management Systems in Biotech Labs
- › 1.5 Examine the Role of Continuous Improvement in ISO 9001
- › 1.6 Implement a Quality Management System: Steps for Biotech Labs

• 2 Key Components of ISO 9001: Structure and Requirements — 6

classes

- › 2.1 Define ISO 9001: Understand the Standard's Purpose and Benefits
- › 2.2 Identify Key Components: Structure of ISO 9001 Explained
- › 2.3 Explore Requirements: Core Principles of Quality Management
- › 2.4 Examine Process Approach: Understanding Systematic Management
- › 2.5 Assess Documentation: Importance of Records and Procedures
- › 2.6 Implement Continuous Improvement: Strategies for Sustaining Quality

• 3 Context of the Organization: Identifying Needs and Expectations

— 6 classes

- › 3.1 Analyze Stakeholder Needs in Biotech Labs
- › 3.2 Map External and Internal Factors Affecting Quality Management
- › 3.3 Identify Compliance Requirements for Quality Standards
- › 3.4 Evaluate Organizational Objectives and Strategic Direction
- › 3.5 Conduct a SWOT Analysis for Quality Improvement
- › 3.6 Develop an Action Plan to Address Stakeholder Expectations

• 4 Quality Objectives and Planning: Setting and Achieving Goals —

6 classes

- › 4.1 Identify Key Quality Objectives in Biotech Labs
- › 4.2 Understand the SMART Criteria for Goal Setting
- › 4.3 Develop Quality Objectives Aligned with ISO 9001 Standards
- › 4.4 Create an Action Plan for Achieving Quality Goals
- › 4.5 Monitor and Measure Progress Towards Quality Objectives
- › 4.6 Adapt and Review Quality Objectives for Continuous Improvement

• 5 Continuous Improvement in Biotechnology: Beyond Compliance

— 6 classes

- › 5.1 Define Continuous Improvement and Its Importance in Biotech
- › 5.2 Explore Key Principles of ISO 9001 in Biotechnology Settings
- › 5.3 Identify Tools and Techniques for Implementing Continuous Improvement
- › 5.4 Assess Current Practices: Gap Analysis for Quality Enhancement
- › 5.5 Develop a Continuous Improvement Plan for Your Lab
- › 5.6 Measure Success: Evaluating the Impact of Continuous Improvement Efforts

• 1 Understanding ISO 9001B Principles in Biotech Leadership — 6

classes

- › 1.1 Define ISO 9001B: Key Principles and Terminology
- › 1.2 Explore the Role of Leadership in Quality Management
- › 1.3 Identify Stakeholder Needs and Expectations in Biotech
- › 1.4 Develop a Quality Management System Framework
- › 1.5 Implement Continuous Improvement Strategies in Labs
- › 1.6 Evaluate Leadership Effectiveness in Quality Outcomes

• 2 Creating a Quality Management Framework in Biotechnology — 6

classes

- › 2.1 Analyze Key Components of a Quality Management Framework
- › 2.2 Identify Regulatory Requirements for Biotechnology Quality Management
- › 2.3 Develop Quality Objectives Aligned with Business Goals
- › 2.4 Establish Processes for Continuous Improvement in Biotech Labs
- › 2.5 Implement Risk Management Strategies in Quality Management
- › 2.6 Evaluate the Effectiveness of Quality Management Practices

• 3 Driving Continuous Improvement through Leadership in Biotech

— 6 classes

- › 3.1 Identify Key Leadership Traits that Drive Continuous Improvement
- › 3.2 Analyze the Role of Leadership in Establishing Quality Culture
- › 3.3 Develop Strategies for Engaging Teams in Quality Initiatives
- › 3.4 Implement Continuous Feedback Loops to Enhance Performance
- › 3.5 Measure the Impact of Leadership on Quality Improvement Projects
- › 3.6 Create a Leadership Action Plan for Sustained Quality Advancement

• 4 Risk Management and Decision-Making in Quality Management —

6 classes

- › 4.1 Identify and Assess Risks in Biotech Quality Management
- › 4.2 Analyze the Impact of Risks on Lab Operations
- › 4.3 Develop Risk Mitigation Strategies for Quality Standards
- › 4.4 Implement Decision-Making Processes in Risk Management
- › 4.5 Evaluate the Effectiveness of Risk Responses and Adjustments
- › 4.6 Foster a Culture of Continuous Improvement in Quality Management

• 5 Leading Change: Adapting to ISO 9001B in Dynamic Biotech Environments — 6 classes

- › 5.1 Identify Key Challenges in Implementing ISO 9001B
- › 5.2 Analyze Stakeholder Roles in Quality Management Transition
- › 5.3 Develop a Change Management Strategy for Biotech Labs
- › 5.4 Foster a Culture of Continuous Improvement in Teams
- › 5.5 Implement Effective Training Programs for ISO 9001B Compliance
- › 5.6 Evaluate the Impact of Change on Lab Performance Metrics

• 1 Understanding Process Improvement in Biotech Labs — 6 classes

- › 1.1 Define Key Concepts of Process Improvement in Biotech
- › 1.2 Identify Common Challenges in Biotech Lab Processes
- › 1.3 Analyze the Impact of Process Improvement on Quality Management
- › 1.4 Explore Tools and Techniques for Effective Process Improvement
- › 1.5 Develop a Process Improvement Plan for a Biotech Lab Scenario
- › 1.6 Evaluate Outcomes and Adjust Strategies for Continuous Improvement

• 2 Key Methodologies for Process Improvement — 6 classes

- › 2.1 Identify Key Process Improvement Methodologies
- › 2.2 Analyze the DMAIC Framework for Quality Enhancement
- › 2.3 Explore Lean Principles for Waste Reduction
- › 2.4 Implement Six Sigma Techniques for Process Optimization
- › 2.5 Utilize the 5 Whys Technique for Root Cause Analysis
- › 2.6 Develop a Process Improvement Plan Using Selected Methodologies

• 3 Identifying and Analyzing Process Inefficiencies — 6 classes

- › 3.1 Identify Key Processes in Biotech Labs
- › 3.2 Recognize Common Process Inefficiencies
- › 3.3 Use Root Cause Analysis to Diagnose Issues
- › 3.4 Measure Process Performance Metrics
- › 3.5 Evaluate Process Mapping Techniques
- › 3.6 Develop Action Plans for Process Improvement

• 4 Implementing Process Changes Effectively — 6 classes

- › 4.1 Assess Current Processes Before Implementing Changes
- › 4.2 Identify Key Stakeholders for Successful Change Management
- › 4.3 Develop a Change Implementation Plan with Clear Objectives
- › 4.4 Communicate Process Changes Effectively to All Team Members
- › 4.5 Monitor and Evaluate the Impact of Process Changes
- › 4.6 Foster a Continuous Improvement Culture Post-Implementation

• 5 Evaluating and Sustaining Process Improvements — 6 classes

- › 5.1 Identify Key Metrics for Evaluating Process Improvements
- › 5.2 Analyze Data Collection Methods for Effective Evaluation
- › 5.3 Assess the Impact of Process Improvements on Lab Operations
- › 5.4 Develop Strategies for Sustaining Process Improvements
- › 5.5 Create a Continuous Improvement Plan for Biotech Labs
- › 5.6 Implement Feedback Mechanisms to Monitor Process Effectiveness

• 1 Foundations of Quality Management Systems in Biotech — 6 classes

- › 1.1 Define Key Concepts of Quality Management Systems in Biotech
- › 1.2 Identify the Role of ISO 9001B in Enhancing Lab Quality
- › 1.3 Explain the Principles of Effective Quality Management
- › 1.4 Discuss the Importance of Compliance and Audit Processes
- › 1.5 Assess Quality Management Challenges in Biotech Labs
- › 1.6 Develop a Strategy for Implementing Quality Control Measures

• 2 ISO 9001B Standards and Frameworks — 6 classes

- › 2.1 Understand ISO 9001B Standards and Their Importance
- › 2.2 Explore the Key Components of ISO 9001B Framework
- › 2.3 Analyze Quality Management Principles in Biotechnology
- › 2.4 Assess Compliance Requirements for Biotech Labs
- › 2.5 Implement Quality Management System Processes
- › 2.6 Evaluate Continuous Improvement Strategies for ISO 9001B

• 3 Implementing Quality Management Processes — 6 classes

- › 3.1 Define Quality Management Processes in Biotech Labs
- › 3.2 Identify Key Components of a Quality Management System
- › 3.3 Assess Current Quality Management Practices
- › 3.4 Develop Effective Quality Control Procedures
- › 3.5 Implement Continuous Improvement Strategies
- › 3.6 Evaluate the Impact of Quality Management on Lab Operations

• 4 Auditing and Assessing Quality Compliance — 6 classes

- › 4.1 Understand ISO 9001B Standards and Principles
- › 4.2 Identify Key Components of Quality Compliance in Biotech
- › 4.3 Learn the Audit Process: Planning and Preparation
- › 4.4 Execute Effective Internal Audits for Quality Management
- › 4.5 Analyze Audit Findings and Identify Non-Conformities
- › 4.6 Develop Action Plans for Continuous Quality Improvement

• 5 Continuous Improvement and Quality Culture in Biotech Labs — 6 classes

- › 5.1 Define Continuous Improvement in Biotech Labs
- › 5.2 Identify Key Elements of a Quality Culture
- › 5.3 Analyze the Role of Leadership in Quality Management
- › 5.4 Develop Strategies for Fostering Team Engagement
- › 5.5 Implement Tools for Measuring Continuous Improvement
- › 5.6 Evaluate Case Studies of Successful Quality Cultures

• 1 Understanding Regulatory Frameworks in Biotechnology — 6

classes

- › 1.1 Define Key Regulatory Terms in Biotechnology
- › 1.2 Identify Major Regulatory Bodies and Their Roles
- › 1.3 Explain the Importance of Regulatory Compliance in Biotech Labs
- › 1.4 Analyze the Impact of Regulatory Changes on Biotechnology Practices
- › 1.5 Evaluate Case Studies of Regulatory Non-compliance in Biotech
- › 1.6 Develop a Compliance Checklist for Biotech Lab Operations

• 2 ISO 9001 Standards Overview and Application — 6 classes

- › 2.1 Define ISO 9001 Standards and Their Importance in Biotech
- › 2.2 Identify Key Components of ISO 9001 Framework
- › 2.3 Explore the Role of Leadership in Quality Management
- › 2.4 Assess Compliance Gaps in Current Biotech Practices
- › 2.5 Develop Action Plans for Implementing ISO 9001 Standards
- › 2.6 Evaluate the Impact of ISO 9001 on Laboratory Performance

• 3 Quality Management Systems: Design and Implementation — 6

classes

- › 3.1 Analyze the Key Components of a Quality Management System
- › 3.2 Design a Quality Policy for Biotech Laboratories
- › 3.3 Develop Procedures for Quality Control in Biotech Labs
- › 3.4 Implement Document Control Practices in Quality Management
- › 3.5 Assess Risk Management Strategies in Quality Systems
- › 3.6 Evaluate the Effectiveness of Quality Management Processes

• 4 Compliance Monitoring and Auditing Techniques — 6 classes

- › 4.1 Identify Compliance Standards and Regulations in Biotech
- › 4.2 Understand Monitoring Techniques for Quality Management
- › 4.3 Explore Internal Auditing Processes in Lab Settings
- › 4.4 Develop Effective Audit Checklists for Compliance
- › 4.5 Analyze Common Audit Findings and Non-Conformance
- › 4.6 Implement Corrective Actions and Continuous Improvement Strategies

• 5 Continuous Improvement Strategies in Regulatory Compliance —

6 classes

- › 5.1 Assess Current Regulatory Compliance Practices
- › 5.2 Identify Key Areas for Continuous Improvement
- › 5.3 Develop Metrics for Measuring Compliance Effectiveness
- › 5.4 Implement a Feedback Loop for Staff Input on Compliance
- › 5.5 Analyze Case Studies of Successful Continuous Improvement
- › 5.6 Create an Action Plan for Sustaining Compliance Enhancements