

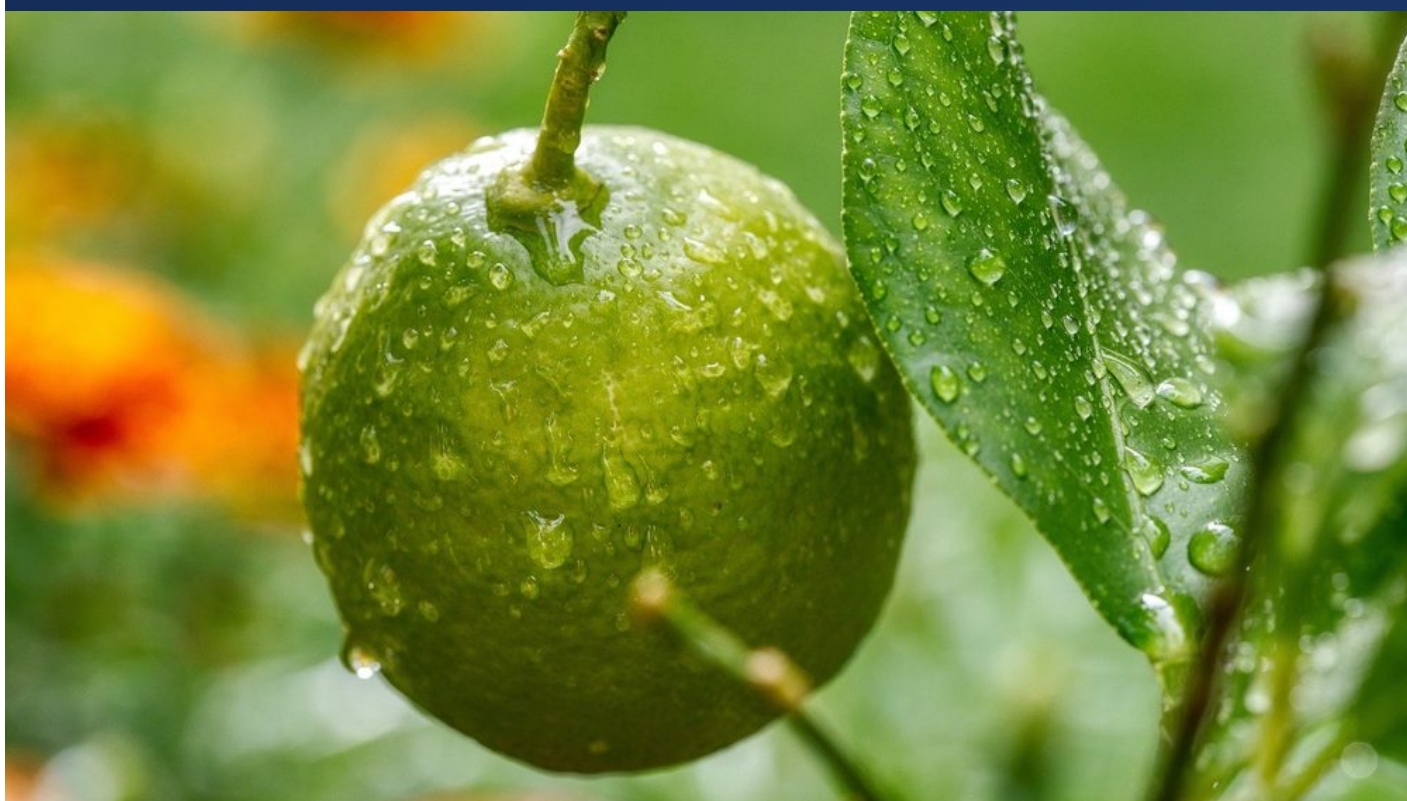
LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 20387 — Biotechnology Biobanking General Requirements

ISO Certification Programme



LAPT — London Academy of Professional Training

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Reference HL-BIO-20387 • ISO Health

UKPRN 10067351 • Registered in England and Wales, company 4984798

AT A GLANCE

REFERENCE	HL-BIO-20387
AWARD	Certificate
ASSESSMENT	430 marks — 258 to pass (60%)
PREREQUISITES	None
VALIDITY	Lifetime
AWARDING BODY	LAPT — London Academy of Professional Training

CURRICULUM

1

Biobanking Standards and Compliance

5 chapters · 30 classes85 marks

• 1 Introduction to Biobanking: Concepts and Importance — 6 classes

› 1.1 Define Biobanking: Understanding the Core Concepts

› 1.2 Explore the Historical Significance of Biobanks in Research

› 1.3 Identify the Key Components of Biobanking Operations

› 1.4 Discuss the Ethical Considerations in Biobanking Practices

› 1.5 Assess the Importance of Biobanking Standards and Compliance

› 1.6 Apply Biobanking Concepts to Real-World Scenarios

• 2 ISO 20387 Overview: Principles and Requirements — 6 classes

› 2.1 Understand the Key Principles of ISO 20387 in Biobanking

› 2.2 Identify the General Requirements for Biobanking Compliance

› 2.3 Assess the Importance of Quality Management Systems in Biobanks

› 2.4 Analyze Risk Management Strategies within Biobanking Standards

› 2.5 Evaluate the Role of Leadership in Implementing ISO 20387

› 2.6 Apply ISO 20387 Standards to Real-World Biobanking Scenarios

• 3 Biobanking Processes and Protocols: Best Practices — 6 classes

› 3.1 Understand Biobanking: Define Key Concepts and Terminology

› 3.2 Identify Essential Biobanking Processes: From Sample Collection to Storage

› 3.3 Examine Regulatory Compliance: Review ISO 20387 Requirements

› 3.4 Implement Best Practices: Develop Standard Operating Procedures (SOPs)

› 3.5 Assess Quality Control Measures: Ensure Sample Integrity and Traceability

› 3.6 Evaluate and Adapt: Continuous Improvement in Biobanking Protocols

• 4 Compliance and Quality Management in Biobanking — 6 classes

› 4.1 Understand the Importance of Compliance in Biobanking

› 4.2 Identify Key Components of Quality Management Systems

› 4.3 Explore ISO 20387 Standards for Biobanking

› 4.4 Assess Risk Management Strategies in Biobanking Operations

› 4.5 Evaluate Quality Control Processes for Biobanking Samples

› 4.6 Implement Continuous Improvement Practices in Biobanking Compliance

• 5 Future Trends in Biobanking: Innovations and Ethical Considerations — 6 classes

› 5.1 Explore Emerging Technologies in Biobanking

› 5.2 Assess Innovative Biobanking Techniques and Their Impact

› 5.3 Analyze Ethical Implications of Biobanking Innovation

› 5.4 Examine Regulatory Changes Affecting Biobanking Practices

› 5.5 Develop Strategies for Implementing New Biobanking Standards

› 5.6 Evaluate Future Trends and Their Influence on Biobanking Compliance

• 1 Fundamentals of Data Management in Biobanking — 6 classes

- › 1.1 Define Core Concepts of Data Management in Biobanking
- › 1.2 Identify Key Data Types and Their Roles in Biobanking
- › 1.3 Explain the Importance of Data Integrity and Quality Control
- › 1.4 Explore Data Security Measures for Biobank Information
- › 1.5 Discuss Regulatory Requirements for Data Management in Biobanking
- › 1.6 Apply Best Practices for Managing Data Throughout the Biobanking Lifecycle

• 2 Data Governance and Compliance in Biotechnology — 6 classes

- › 2.1 Define Data Governance Principles in Biotechnology
- › 2.2 Identify Key Regulations Affecting Biobanking Operations
- › 2.3 Evaluate Compliance Requirements for Biobanks
- › 2.4 Implement Data Management Best Practices in Biotechnology
- › 2.5 Assess Risks and Challenges in Data Security
- › 2.6 Develop a Data Governance Framework for Biobanking

• 3 Data Security Protocols for Biobanks — 6 classes

- › 3.1 Identify Key Data Security Risks in Biobanks
- › 3.2 Analyze Data Security Protocols for Compliance with ISO 20387
- › 3.3 Evaluate the Role of Encryption in Biobank Data Security
- › 3.4 Implement Access Control Measures for Sensitive Biobank Data
- › 3.5 Develop Incident Response Plans for Data Breaches in Biobanks
- › 3.6 Assess the Effectiveness of Data Security Training for Biobank Staff

• 4 Data Integrity and Quality Assurance in Biobanking — 6 classes

- › 4.1 Understand Data Integrity Principles in Biobanking
- › 4.2 Identify Common Sources of Data Quality Issues
- › 4.3 Implement Data Validation Techniques for Accuracy
- › 4.4 Evaluate the Role of Standard Operating Procedures (SOPs) in Quality Assurance
- › 4.5 Analyze Case Studies of Data Breaches and Their Impact
- › 4.6 Develop a Data Management Plan to Enhance Security and Integrity

• 5 Advanced Data Management Strategies for Biobank Operations — 6 classes

- › 5.1 Assess Data Quality Standards for Biobank Operations
- › 5.2 Implement Data Governance Frameworks in Biobanks
- › 5.3 Utilize Advanced Data Encryption Techniques for Security
- › 5.4 Develop Protocols for Data Sharing and Accessibility
- › 5.5 Analyze Data Integrity and Compliance Challenges
- › 5.6 Create a Comprehensive Data Management Plan for Biobanks

• 1 Understanding Biobanking: Concepts and Frameworks — 6 classes

- › 1.1 Define Biobanking and Its Importance in Biotechnology
- › 1.2 Identify Key Concepts and Terminologies in Biobanking
- › 1.3 Explore the Frameworks and Standards Governing Biobanking Operations
- › 1.4 Examine the Role of Ethics and Regulations in Biobanking
- › 1.5 Analyze Case Studies of Successful Biobanking Initiatives
- › 1.6 Develop a Strategic Plan for Implementing a Biobanking Project

• 2 Project Lifecycle in Biobanking: Stages and Methodologies — 6 classes

- › 2.1 Define the Key Stages in the Biobanking Project Lifecycle
- › 2.2 Identify Methodologies for Effective Project Planning in Biobanking
- › 2.3 Assess Risk Management Strategies in Biobanking Projects
- › 2.4 Develop a Stakeholder Engagement Plan for Biobanking Projects
- › 2.5 Implement Monitoring Techniques for Biobanking Project Progress
- › 2.6 Evaluate Project Outcomes and Continuous Improvement in Biobanking

• 3 Stakeholder Engagement and Communication in Biobanking Projects — 6 classes

- › 3.1 Identify Key Stakeholders in Biobanking Projects
- › 3.2 Analyze Stakeholder Needs and Expectations
- › 3.3 Develop Effective Communication Strategies for Biobanking
- › 3.4 Facilitate Stakeholder Engagement through Workshops
- › 3.5 Evaluate the Impact of Communication on Stakeholder Relationships
- › 3.6 Implement Feedback Mechanisms for Continuous Improvement

• 4 Risk Management Strategies in Biobanking Projects — 6 classes

- › 4.1 Identify and Assess Key Risks in Biobanking Projects
- › 4.2 Explore Risk Management Frameworks for Biobanking
- › 4.3 Develop Contingency Plans for Common Biobanking Risks
- › 4.4 Implement Risk Mitigation Strategies in Biobanking Operations
- › 4.5 Monitor and Review Risks in Biobanking Projects
- › 4.6 Communicate Risk Management Plans to Stakeholders

• 5 Evaluation and Continuous Improvement in Biobanking Projects — 6 classes

- › 5.1 Define Key Performance Indicators for Biobanking Projects
- › 5.2 Conduct a SWOT Analysis for Continuous Improvement
- › 5.3 Implement Feedback Mechanisms in Biobanking Processes
- › 5.4 Analyze Data to Identify Improvement Opportunities
- › 5.5 Develop an Action Plan for Implementing Changes
- › 5.6 Evaluate the Effectiveness of Improvement Initiatives

• 1 Understanding Biobanking: Concepts and Key Components — 6 classes

- › 1.1 Define Biobanking and Its Importance in Biotechnology
- › 1.2 Identify Key Components of a Biobanking System
- › 1.3 Explore the Roles and Responsibilities in Biobanking Operations
- › 1.4 Assess Quality Management Standards in Biobanking
- › 1.5 Examine Ethical Considerations in Biobanking Practices
- › 1.6 Apply Best Practices for Quality Assurance in Biobanking

• 2 ISO 20387: Framework and Quality Management Principles — 6 classes

- › 2.1 Define and Explain the ISO 20387 Framework in Biobanking
- › 2.2 Identify Key Quality Management Principles in Biotechnology
- › 2.3 Discuss the Importance of Compliance with ISO 20387 Standards
- › 2.4 Analyze the Role of Leadership in Implementing Quality Management
- › 2.5 Evaluate Strategies for Continuous Improvement in Biobanking
- › 2.6 Develop an Action Plan to Align Biobanking Practices with ISO 20387

• 3 Quality Assurance Systems in Biobanking — 6 classes

- › 3.1 Define Quality Assurance in Biobanking Contexts
- › 3.2 Identify Key Components of Quality Management Systems
- › 3.3 Explore ISO 20387 Standards and Their Implementation
- › 3.4 Assess Risk Management Strategies in Biobanking
- › 3.5 Develop Internal Audit Procedures for Quality Assurance
- › 3.6 Evaluate Continuous Improvement Practices in Biobanking

• 4 Risk Management and Compliance in Biobanking — 6 classes

- › 4.1 Identify Key Risks in Biobanking Operations
- › 4.2 Assess Compliance Requirements for Biobanking Standards
- › 4.3 Develop a Risk Management Framework for Biobanks
- › 4.4 Implement Risk Mitigation Strategies in Biobanking
- › 4.5 Monitor and Review Compliance Status in Biobanking
- › 4.6 Foster a Culture of Risk Awareness in Biobanking Teams

• 5 Continuous Improvement and Best Practices in Biobanking Quality Management — 6 classes

- › 5.1 Identify Key Components of Continuous Improvement in Biobanking
- › 5.2 Analyze Common Challenges in Biobanking Quality Management
- › 5.3 Explore Best Practices for Quality Assurance in Biobanking
- › 5.4 Implement Effective Training Programs for Biobanking Staff
- › 5.5 Evaluate the Impact of Quality Management Systems on Biobank Efficiency
- › 5.6 Develop Action Plans for Sustaining Continuous Improvement in Biobanking

• 1 Foundations of Research Ethics in Biotechnology — 6 classes

- › 1.1 Define Key Terms in Research Ethics
- › 1.2 Explore the Importance of Informed Consent
- › 1.3 Identify Ethical Principles in Biotechnology Research
- › 1.4 Analyze Case Studies of Ethical Dilemmas in Biobanking
- › 1.5 Discuss Regulatory Frameworks Governing Biobanking
- › 1.6 Evaluate Best Practices for Ethical Biotechnology Research

• 2 Understanding Regulatory Frameworks in Biotechnology Research — 6 classes

- › 2.1 Define the Regulatory Frameworks Guiding Biotechnology Research
- › 2.2 Identify Key Regulatory Bodies and Their Roles in Biobanking
- › 2.3 Examine Ethical Considerations in Biotechnology Research Regulations
- › 2.4 Analyze Case Studies of Regulatory Compliance in Biobanking
- › 2.5 Discuss the Impact of Non-Compliance on Biobanking Practices
- › 2.6 Develop a Compliance Checklist for Biotechnology Research Projects

• 3 Informed Consent Processes for Biobanking — 6 classes

- › 3.1 Define Informed Consent in the Context of Biobanking
- › 3.2 Identify Key Components of an Informed Consent Form
- › 3.3 Discuss Ethical Considerations in Informed Consent
- › 3.4 Explore the Role of Participant Autonomy in Consent Processes
- › 3.5 Analyze Case Studies of Informed Consent in Biobanking
- › 3.6 Develop a Simple Informed Consent Template for a Biobank

• 4 Data Protection and Confidentiality in Biobanking — 6 classes

- › 4.1 Understand Data Protection Principles in Biobanking
- › 4.2 Identify Key Regulations Governing Biobank Data
- › 4.3 Assess Risks to Data Privacy in Biobanking
- › 4.4 Explore Informed Consent in Data Handling
- › 4.5 Utilize Best Practices for Data Confidentiality
- › 4.6 Implement Data Protection Strategies in Biobank Operations

• 5 Ethical Dilemmas and Case Studies in Biotechnology Biobanking — 6 classes

- › 5.1 Identify Key Ethical Principles in Biobanking
- › 5.2 Analyze Common Ethical Dilemmas in Biobanking Scenarios
- › 5.3 Evaluate Case Studies on Informed Consent in Biotechnology
- › 5.4 Discuss the Role of Privacy and Confidentiality in Biobanking
- › 5.5 Propose Solutions to Ethical Challenges in Biobanking Case Studies
- › 5.6 Assess the Impact of Ethical Decision-Making in Biobanking Outcomes

• 1 Understanding Biobanking: Principles and Practices — 6 classes

- › 1.1 Define Biobanking and Its Importance in Biotechnology
- › 1.2 Identify Key Components of Biobank Infrastructure
- › 1.3 Explore Ethical Considerations in Biobanking Practices
- › 1.4 Analyze Regulatory Frameworks Governing Biobanking
- › 1.5 Assess Quality Management Systems in Biobanking
- › 1.6 Develop a Strategic Plan for Effective Biobank Leadership

• 2 Regulatory Frameworks and ISO Standards in Biobanking — 6 classes

- › 2.1 Analyze the Importance of Regulatory Frameworks in Biobanking
- › 2.2 Examine Key ISO Standards Relevant to Biobanking
- › 2.3 Identify the Requirements of ISO 20387 for Biobanking Practices
- › 2.4 Evaluate the Impact of Compliance on Biobanking Operations
- › 2.5 Develop a Compliance Checklist Based on ISO Standards
- › 2.6 Create a Strategic Plan to Implement ISO 20387 in Your Biobank

• 3 Strategic Planning for Biobanking Operations — 6 classes

- › 3.1 Analyze Current Trends in Biobanking Operations
- › 3.2 Define Strategic Goals for Biobanking Initiatives
- › 3.3 Assess Stakeholder Needs in Biobanking Strategies
- › 3.4 Develop Actionable Plans for Biobanking Implementation
- › 3.5 Evaluate Risk Management Strategies in Biobanking
- › 3.6 Create Performance Metrics for Strategic Success in Biobanking

• 4 Leadership and Team Management in Biobanking — 6 classes

- › 4.1 Define Effective Leadership Traits in Biobanking
- › 4.2 Identify Key Roles in Biobanking Teams
- › 4.3 Analyze Team Dynamics and Communication Strategies
- › 4.4 Develop Conflict Resolution Techniques for Teams
- › 4.5 Implement Decision-Making Processes in Biobanking
- › 4.6 Assess Leadership Impact on Biobanking Outcomes

• 5 Innovation and Future Trends in Biobanking Leadership — 6 classes

- › 5.1 Evaluate Emerging Technologies Impacting Biobanking Leadership
- › 5.2 Analyze Regulatory Changes Shaping Biobanking Innovation
- › 5.3 Explore Collaborative Models to Enhance Biobanking Practices
- › 5.4 Develop Strategic Plans for Implementing Innovative Solutions
- › 5.5 Assess the Role of Data Management in Future Biobanking Trends
- › 5.6 Create Actionable Recommendations for Leading Change in Biobanking