

LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 13528 — Statistical Methods for Proficiency Testing

ISO Certification Programme



LAPT — London Academy of Professional Training

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Reference HL-BIO-13528 • ISO Health

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AT A GLANCE

REFERENCE	HL-BIO-13528
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 classes65 marks

• 1 Introduction to Data Analysis in Proficiency Testing — 6 classes

› 1.1 Define Key Concepts in Proficiency Testing

› 1.2 Explore the Importance of Data Analysis in Proficiency Testing

› 1.3 Identify Common Statistical Methods Used in Data Analysis

› 1.4 Evaluate the Role of ISO 13528 in Statistical Methods

› 1.5 Analyze Sample Data Sets for Proficiency Testing

› 1.6 Apply Data Analysis Techniques to Real-World Scenarios

• 2 Statistical Principles and Techniques for Data Evaluation — 6 classes

› 2.1 Understand Key Statistical Concepts for Data Evaluation

› 2.2 Explore Descriptive Statistics in Data Analysis

› 2.3 Apply Inferential Statistics for Proficiency Testing

› 2.4 Analyze Variability and Its Impact on Data Interpretation

› 2.5 Evaluate Quality Assurance Metrics Using Statistical Methods

› 2.6 Implement Statistical Techniques for Improved Decision Making

• 3 Designing and Implementing Proficiency Testing Schemes — 6 classes

› 3.1 Define Objectives for Proficiency Testing Schemes

› 3.2 Identify Key Stakeholders and their Roles

› 3.3 Develop Statistical Methodologies for Data Collection

› 3.4 Design Sample Selection Procedures and Criteria

› 3.5 Implement Data Analysis Techniques for Result Interpretation

› 3.6 Evaluate and Revise Proficiency Testing Schemes Based on Feedback

• 4 Advanced Statistical Methods for Data Interpretation — 6 classes

› 4.1 Explore Advanced Data Visualization Techniques

› 4.2 Analyze Variability Using Statistical Process Control

› 4.3 Apply Multivariate Analysis for Complex Datasets

› 4.4 Interpret Results of Hypothesis Testing in Proficiency Studies

› 4.5 Evaluate Measurement Uncertainty in Data Interpretation

› 4.6 Implement Statistical Models for Predictive Analysis

• 5 Reporting and Communicating Data Analysis Results — 6 classes

› 5.1 Identify Key Data Analysis Results for Reporting

› 5.2 Choose Appropriate Visualizations for Data Communication

› 5.3 Craft Clear and Concise Written Summaries of Findings

› 5.4 Tailor Reports to Different Stakeholder Needs

› 5.5 Incorporate Statistical Significance into Report Discussions

› 5.6 Present Data Analysis Findings Effectively to an Audience

• 1 Fundamentals of Proficiency Testing in Biotechnology — 6 classes

- › 1.1 Define the Key Concepts of Proficiency Testing in Biotechnology
- › 1.2 Identify the Objectives and Benefits of Proficiency Testing Programs
- › 1.3 Explore Different Types of Proficiency Testing Designs
- › 1.4 Assess the Role of Statistical Methods in Proficiency Testing
- › 1.5 Develop a Framework for Implementing Proficiency Testing Programs
- › 1.6 Evaluate Case Studies of Successful Proficiency Testing in Biotechnology

• 2 ISO 13528 Standards and Guidelines — 6 classes

- › 2.1 Identify Key Components of ISO 13528 Standards
- › 2.2 Analyze the Role of Proficiency Testing in Quality Assurance
- › 2.3 Evaluate Statistical Methods for Data Interpretation
- › 2.4 Design a Proficiency Testing Program Framework
- › 2.5 Implement Best Practices for Test Design and Administration
- › 2.6 Review Case Studies to Enhance Proficiency Testing Strategies

• 3 Designing Effective Proficiency Testing Programs — 6 classes

- › 3.1 Identify Key Components of Proficiency Testing Programs
- › 3.2 Analyze Stakeholder Needs for Effective Program Design
- › 3.3 Develop Objectives and Goals for Proficiency Testing
- › 3.4 Create a Framework for Sample Selection and Distribution
- › 3.5 Implement Evaluation Criteria for Test Outcomes
- › 3.6 Design a Continuous Improvement Process for Proficiency Testing

• 4 Statistical Analysis of Proficiency Testing Data — 6 classes

- › 4.1 Analyze the Distribution of Proficiency Testing Data
- › 4.2 Identify Key Statistical Measures for Data Interpretation
- › 4.3 Assess Variability and Its Impact on Proficiency Outcomes
- › 4.4 Apply Statistical Tests for Evaluating Proficiency Results
- › 4.5 Interpret Results from Proficiency Testing Using Statistical Software
- › 4.6 Develop Actionable Insights from Statistical Analysis for Program Improvement

• 5 Continuous Improvement and Evaluation of Testing Programs — 6 classes

- › 5.1 Assess Current Proficiency Testing Programs
- › 5.2 Identify Key Performance Indicators for Evaluation
- › 5.3 Analyze Data for Continuous Improvement
- › 5.4 Develop Action Plans Based on Findings
- › 5.5 Implement Changes to Enhance Testing Programs
- › 5.6 Review and Reflect on Program Effectiveness

• 1 Understanding Leadership Principles in Proficiency Testing — 6 classes

- › 1.1 Define Leadership Roles in Proficiency Testing
- › 1.2 Analyze Key Leadership Styles Impacting Proficiency Testing
- › 1.3 Identify Critical Risk Factors in Proficiency Testing Environments
- › 1.4 Develop Strategies for Effective Leadership in Risk Management
- › 1.5 Evaluate Case Studies on Leadership Success in Proficiency Testing
- › 1.6 Create an Action Plan for Implementing Leadership Principles

• 2 The Role of Leadership in Creating a Risk-Aware Culture — 6 classes

- › 2.1 Define Risk Awareness and Its Importance in Leadership
- › 2.2 Identify Key Leadership Traits That Foster a Risk-Aware Culture
- › 2.3 Assess Current Organizational Culture Regarding Risk Management
- › 2.4 Develop Strategies to Enhance Risk Communication Among Teams
- › 2.5 Implement Leadership Practices That Encourage Proactive Risk Management
- › 2.6 Evaluate the Impact of Leadership on Risk-Aware Culture Over Time

• 3 Identifying and Assessing Risks in Biotechnology Testing — 6 classes

- › 3.1 Define and Categorize Risks in Biotechnology Testing
- › 3.2 Analyze Risk Factors Affecting Biotechnology Testing Outcomes
- › 3.3 Evaluate the Impact of Identified Risks on Testing Processes
- › 3.4 Prioritize Risks Based on Likelihood and Consequences
- › 3.5 Develop Mitigation Strategies for High-Priority Risks
- › 3.6 Implement Risk Assessment Findings in Biotechnology Testing Protocols

• 4 Developing Risk Management Strategies for Proficiency Testing — 6 classes

- › 4.1 Identify Key Risk Factors in Proficiency Testing
- › 4.2 Assess the Impact of Risks on Testing Outcomes
- › 4.3 Develop Comprehensive Risk Mitigation Strategies
- › 4.4 Create a Risk Management Plan for Proficiency Testing
- › 4.5 Evaluate Effectiveness of Risk Mitigation Measures
- › 4.6 Communicate Risk Management Strategies to Stakeholders

• 5 Leadership in Crisis Management and Risk Mitigation — 6 classes

- › 5.1 Assessing Organizational Vulnerabilities in Crisis Situations
- › 5.2 Developing Leadership Skills for Effective Crisis Communication
- › 5.3 Implementing Risk Mitigation Strategies in Uncertain Environments
- › 5.4 Fostering Team Resilience During Times of Crisis
- › 5.5 Evaluating the Effectiveness of Crisis Management Protocols
- › 5.6 Creating a Comprehensive Crisis Management Plan for Leadership

• 1 Understanding ISO 13528: Framework and Key Concepts — 6

classes

- › 1.1 Define ISO 13528 and Its Importance in Proficiency Testing
- › 1.2 Explore the Framework of ISO 13528 Standards
- › 1.3 Identify Key Concepts and Terminology in ISO 13528
- › 1.4 Analyze the Roles and Responsibilities in Proficiency Testing
- › 1.5 Examine Case Studies of ISO 13528 Implementation
- › 1.6 Develop an Action Plan for Implementing ISO 13528 in Your Organization

• 2 Designing Proficiency Testing Programs: Implementation**Strategies** — 6 classes

- › 2.1 Identify Key Principles of Proficiency Testing Frameworks
- › 2.2 Assess the Requirements for Designing Proficiency Testing Programs
- › 2.3 Develop Protocols for Sample Selection and Distribution
- › 2.4 Implement Statistical Methods for Data Analysis in Proficiency Testing
- › 2.5 Evaluate Outcomes and Determine Actions Based on Proficiency Test Results
- › 2.6 Create a Continuous Improvement Plan for Proficiency Testing Programs

• 3 Data Collection Techniques: Ensuring Validity and Reliability — 6

classes

- › 3.1 Identify Key Principles of Data Validity
- › 3.2 Explore Common Data Collection Techniques
- › 3.3 Differentiate Between Qualitative and Quantitative Data
- › 3.4 Assess Reliability in Data Collection Methods
- › 3.5 Implement Strategies for Enhancing Data Validity
- › 3.6 Evaluate Real-World Case Studies on Data Reliability

• 4 Statistical Analysis in Proficiency Testing: Tools and Applications

— 6 classes

- › 4.1 Understand the Basics of Proficiency Testing and ISO 13528
- › 4.2 Explore Statistical Tools for Data Analysis in Proficiency Testing
- › 4.3 Apply Descriptive Statistics to Proficiency Testing Results
- › 4.4 Utilize Control Charts for Monitoring Performance in Proficiency Testing
- › 4.5 Interpret Results Using Z-Scores and Performance Ratios
- › 4.6 Implement Continuous Improvement Strategies Based on Statistical Analysis

• 5 Reporting Results and Continuous Improvement: Best Practices

— 6 classes

- › 5.1 Analyze Reporting Requirements for ISO 13528 Compliance
- › 5.2 Develop Clear Result Interpretation Guidelines
- › 5.3 Implement Best Practices for Reporting Findings
- › 5.4 Facilitate Stakeholder Engagement through Effective Communication
- › 5.5 Establish Metrics for Continuous Improvement in Reporting
- › 5.6 Evaluate Reporting Strategies for Enhanced Proficiency Testing

• 1 Understanding Quality Assurance Principles in Biotechnology —

6 classes

- › 1.1 Define Key Quality Assurance Concepts in Biotechnology
- › 1.2 Explore the Importance of Quality Assurance in Biotechnology Practices
- › 1.3 Identify Regulatory Standards Impacting Quality Assurance in Biotechnology
- › 1.4 Examine Roles and Responsibilities in Quality Assurance Systems
- › 1.5 Analyze Case Studies of Quality Assurance Failures in Biotechnology
- › 1.6 Develop a Quality Assurance Checklist for Biotechnology Applications

• 2 Exploring ISO Standards Applicable to Biotechnology — 6 classes

- › 2.1 Identify Key ISO Standards in Biotechnology
- › 2.2 Explain the Importance of Quality Assurance in Biotechnology
- › 2.3 Analyze the Role of ISO 13528 in Proficiency Testing
- › 2.4 Discuss Compliance Requirements for Biotech Laboratories
- › 2.5 Evaluate Case Studies on ISO Implementation in Biotechnology
- › 2.6 Develop a Quality Assurance Plan Based on ISO Standards

• 3 Implementing Quality Assurance Frameworks in Biotechnology Labs — 6 classes

- › 3.1 Identify Key Components of Quality Assurance Frameworks in Biotechnology Labs
- › 3.2 Assess the Role of ISO 13528 in Proficiency Testing Procedures
- › 3.3 Develop Standard Operating Procedures for Quality Assurance
- › 3.4 Evaluate Metrics for Measuring Quality Assurance Effectiveness
- › 3.5 Implement Continuous Improvement Strategies in Quality Assurance
- › 3.6 Design a Proficiency Testing Program for Biotechnology Applications

• 4 Statistical Methods for Evaluating Proficiency Testing Outcomes

— 6 classes

- › 4.1 Understand the Importance of Proficiency Testing in Biotechnology
- › 4.2 Explore Key Statistical Concepts for Proficiency Testing Outcomes
- › 4.3 Analyze Data Distributions in Proficiency Testing Scenarios
- › 4.4 Apply Statistical Methods for Measuring Variability in Test Results
- › 4.5 Interpret Proficiency Testing Results Using Confidence Intervals
- › 4.6 Evaluate and Report on the Effectiveness of Proficiency Testing Programs

• 5 Leadership in Quality Assurance: Driving Continuous Improvement — 6 classes

- › 5.1 Understand Key Principles of Quality Assurance in Biotechnology
- › 5.2 Explore the Role of Leadership in Driving Quality Improvement
- › 5.3 Analyze Case Studies of Successful Quality Assurance Programs
- › 5.4 Implement Effective Communication Strategies in Quality Teams
- › 5.5 Develop Tools for Measuring Continuous Improvement in QA
- › 5.6 Create an Action Plan for Leading Quality Assurance Initiatives

• 1 Fundamentals of Statistical Theory in Proficiency Testing — 6

classes

- › 1.1 Define Key Concepts in Statistical Theory for Proficiency Testing
- › 1.2 Explore the Role of Variability in Proficiency Testing Results
- › 1.3 Analyze Measurement Uncertainty and Its Impact on Testing
- › 1.4 Apply Statistical Distributions to Interpret Proficiency Data
- › 1.5 Examine Techniques for Establishing Acceptance Criteria
- › 1.6 Implement Statistical Tools for Evaluating Proficiency Testing Outcomes

• 2 Descriptive Statistics and Data Visualization Techniques — 6

classes

- › 2.1 Define and Differentiate Between Measures of Central Tendency
- › 2.2 Explore Measures of Dispersion: Range, Variance, and Standard Deviation
- › 2.3 Apply Data Visualization Techniques: Creating Histograms and Box Plots
- › 2.4 Analyze Data Distributions: Normality and Skewness Assessment
- › 2.5 Interpret Data Visualizations: Understanding and Communicating Insights
- › 2.6 Develop a Comprehensive Report Using Descriptive Statistics and Visuals

• 3 Inferential Statistics and Hypothesis Testing — 6

- › 3.1 Define Inferential Statistics and Its Importance in Proficiency Testing
- › 3.2 Explore Key Concepts of Hypothesis Testing in Statistical Analysis
- › 3.3 Identify Null and Alternative Hypotheses in Experimental Design
- › 3.4 Calculate and Interpret p-Values in Hypothesis Testing Scenarios
- › 3.5 Apply Type I and Type II Errors in Real-World Testing Cases
- › 3.6 Conduct a Hypothesis Test: Step-by-Step Application in Proficiency Testing

• 4 Analysis of Variance (ANOVA) and Its Application — 6

- › 4.1 Understand the Fundamentals of ANOVA
- › 4.2 Identify Different Types of ANOVA Techniques
- › 4.3 Conduct a One-Way ANOVA: Step-by-Step
- › 4.4 Interpret ANOVA Results: P-Values and F-Statistics
- › 4.5 Explore Post Hoc Tests for ANOVA Analysis
- › 4.6 Apply ANOVA to Real-World Proficiency Testing Scenarios

• 5 Advanced Statistical Methods and Quality Control in Biotechnology — 6

classes

- › 5.1 Analyze the Role of Statistical Methods in Proficiency Testing
- › 5.2 Explore Advanced Statistical Techniques in Biotechnology
- › 5.3 Implement Quality Control Protocols Using Statistical Analysis
- › 5.4 Evaluate the Impact of Statistical Variability on Biotechnological Processes
- › 5.5 Design Proficiency Testing Programs with Statistical Rigor
- › 5.6 Apply Statistical Software Tools for Data Interpretation in Biotechnology