Method Validation and Verification Training Course

Professional Development Training Course Outline

Category	General Training	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Method Validation and Verification are critical components of modern laboratory quality management systems, ensuring that analytical methods consistently produce accurate, reliable, reproducible, and compliant results. In highly regulated industries such as pharmaceuticals, biotechnology, food and beverage, environmental testing, petrochemicals, clinical laboratories, and manufacturing, robust method validation frameworks are essential for meeting regulatory requirements and maintaining data integrity. Method Validation and Verification Training Course provides comprehensive knowledge of analytical method lifecycle management, validation protocols, measurement uncertainty, risk-based approaches, statistical evaluation, quality assurance, and compliance with international standards and GMP requirements.

Participants will gain practical expertise in designing validation studies, establishing performance characteristics, conducting method verification, evaluating precision and accuracy, determining detection limits, and managing validation documentation. The course integrates industry best practices, digital laboratory technologies, advanced statistical tools, regulatory expectations, and real-world case studies to enhance laboratory performance, improve audit readiness, strengthen regulatory compliance, and support continuous improvement initiatives. Emphasis is placed on data-driven decision-making, quality risk management, laboratory excellence, and operational efficiency.

Programme Curriculum

Method Validation and Verification Training Course

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Course Objectives

By the end of this training program, participants will be able to:

1. Understand global regulatory requirements for method validation and verification.
2. Apply risk-based validation strategies using modern quality frameworks.
3. Design comprehensive validation and verification protocols.
4. Evaluate analytical method performance characteristics effectively.
5. Establish accuracy, precision, specificity, and robustness parameters.
6. Determine detection limits and quantitation limits using statistical approaches.
7. Perform measurement uncertainty assessments and calculations.
8. Implement data integrity and ALCOA+ principles in validation activities.
9. Conduct method transfer and cross-laboratory verification studies.
10. Utilize advanced statistical tools for validation data analysis.
11. Develop compliant validation reports and technical documentation.
12. Improve laboratory quality systems through continuous validation practices.
13. Ensure audit readiness and regulatory compliance across laboratory operations.

Target Audience

1. Laboratory Managers
2. Quality Assurance Professionals
3. Quality Control Analysts
4. Analytical Chemists
5. Validation Specialists
6. Regulatory Affairs Personnel
7. Microbiology Laboratory Staff
8. Technical Managers and Laboratory Supervisors

Course Modules

Module 1: Fundamentals of Method Validation and Verification

- Principles of analytical method validation

- Validation versus verification concepts
- Regulatory expectations and requirements
- Method lifecycle management
- Validation planning strategies
- **Case Study:** Establishing a validation framework for a pharmaceutical QC laboratory.

Module 2: Regulatory Guidelines and Standards

- ICH Q2(R2) requirements
- ISO/IEC 17025 compliance
- FDA and GMP expectations
- USP and EP guidance
- Documentation requirements
- **Case Study:** Regulatory inspection findings related to inadequate validation.

Module 3: Validation Planning and Protocol Development

- Validation master plans
- Protocol design methodologies
- Acceptance criteria establishment
- Risk assessment techniques
- Resource allocation
- **Case Study:** Developing a validation protocol for a new analytical method.

Module 4: Accuracy and Precision Assessment

- Accuracy determination techniques
- Repeatability studies
- Intermediate precision evaluation
- Reproducibility assessment
- Statistical analysis methods
- **Case Study:** Precision failure investigation in analytical testing.

Module 5: Specificity and Selectivity Evaluation

- Interference assessment
- Matrix effect studies
- Impurity profiling
- Selectivity testing
- Method discrimination capability
- **Case Study:** Specificity evaluation for complex pharmaceutical formulations.

Module 6: Linearity and Range Determination

- Calibration model development
- Regression analysis techniques
- Working range establishment
- Correlation assessment
- Data interpretation
- **Case Study:** Establishing linearity for trace contaminant analysis.

Module 7: Detection and Quantitation Limits

- LOD determination methods
- LOQ calculation approaches
- Signal-to-noise techniques
- Statistical estimation methods
- Practical applications
- **Case Study:** Determining detection limits in environmental testing.

Module 8: Robustness and Ruggedness Studies

- Robustness testing principles
- Experimental design approaches
- Critical parameter identification
- Ruggedness evaluations
- Risk mitigation strategies
- **Case Study:** Assessing robustness of HPLC analytical methods.

Module 9: Method Verification Processes

- Verification requirements
- Laboratory implementation procedures
- Performance confirmation studies
- Verification documentation
- Acceptance criteria evaluation
- **Case Study:** Verification of a compendial analytical method.

Module 10: Measurement Uncertainty

- Sources of uncertainty
- Uncertainty estimation models
- Quantitative calculations
- Uncertainty budgets
- Reporting requirements
- **Case Study:** Measurement uncertainty estimation in calibration laboratories.

Module 11: Statistical Tools for Validation

- Descriptive statistics
- ANOVA applications
- Regression techniques
- Control chart utilization
- Trend analysis methods
- **Case Study:** Statistical evaluation of validation datasets.

Module 12: Method Transfer and Comparative Studies

- Transfer protocols
- Receiving laboratory qualification
- Equivalency assessment
- Comparative testing
- Performance monitoring
- **Case Study:** Global method transfer between manufacturing sites.

Module 13: Documentation and Data Integrity

- Validation report preparation
- ALCOA+ principles
- Electronic records compliance
- Audit trail reviews
- Document control systems
- **Case Study:** Data integrity remediation in validation records.

Module 14: Quality Risk Management in Validation

- Risk identification methodologies
- FMEA applications
- Critical control points
- Risk mitigation planning
- Continuous improvement
- **Case Study:** Risk-based validation of a high-impact analytical method.

Module 15: Audits, Inspections and Continuous Improvement

- Internal audit preparation
- Regulatory inspection readiness
- CAPA implementation
- Validation lifecycle review
- Continuous improvement strategies
- **Case Study:** Successful response to a regulatory laboratory inspection.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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