Advanced Statistical Analysis for Method Development Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

In the highly regulated environments of pharmaceuticals, biotechnology, and analytical laboratories, the development of new methods demands an uncompromised foundation of scientific validity and data integrity. The traditional "trial-and-error" approach is not only inefficient but also fails to meet modern ICH Q2(R1) and ICH Q14/Q2(R2) guidelines, especially regarding Quality by Design (QbD) principles. Advanced Statistical Analysis for Method Development Training Course addresses the critical industry need for professionals skilled in applying sophisticated statistical methodologies to method development and validation. Participants will transition from basic statistics to mastering techniques like Design of Experiments, measurement uncertainty (MU) estimation following ISO GUM, and chemometrics, enabling a truly risk-based approach to method lifecycle management.

This intensive program is engineered to build analytical robustness and method performance right from the development phase. By focusing on advanced modeling, optimization, and multivariate data analysis, the course empowers scientists to reduce development time, minimize costly re-work, and ensure regulatory compliance. Graduates will be equipped to develop high-quality, reliable, and consistent analytical procedures that stand up to the most rigorous audits, ultimately accelerating time-to-market for new products and significantly improving operational efficiency within the laboratory.

Programme Curriculum

Advanced Statistical Analysis for Method Development Training Course

Introduction

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Course Duration

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Course Objectives

1. Master the application of Design of Experiments (DoE), including factorial and response surface methodology (RSM), for method optimization and ruggedness testing.
2. Quantify and report Measurement Uncertainty (MU) in accordance with the ISO GUM framework for critical analytical results.
3. Implement the principles of Analytical Quality by Design to define the Analytical Target Profile (ATP) and Method Operable Design Region.
4. Perform multivariate data analysis and chemometrics for complex data interpretation, pattern recognition, and spectral method development.
5. Utilize advanced regression modeling for establishing linearity, calibration curves, and process capability assessment.
6. Apply statistical tests for rigorous method comparison, transfer, and specification setting.
7. Calculate and interpret key validation parameters using confidence intervals and tolerance intervals.
8. Develop robust System Suitability Tests and Statistical Quality Control (SQC) charts for routine method monitoring and process stability.
9. Employ statistical software for efficient data handling, scripting, and data visualization.
10. Evaluate sources of variability and their impact on overall method performance and risk assessment.
11. Conduct statistical analysis for stability studies and forced degradation studies.
12. Interpret regulatory expectations from ICH Q2(R1), ICH Q14, and USP chapters concerning the statistical aspects of analytical procedures.
13. Streamline method lifecycle management by statistically justifying revalidation and method improvements under a control strategy.

Target Audience

1. Analytical Chemists and Scientists (R&D, QC, and Manufacturing Support).
2. Method Validation Specialists and Engineers.
3. Quality Assurance (QA) and Quality Control (QC) personnel.

4. Regulatory Affairs and CMC Documentation Specialists.
5. Laboratory Managers and Supervisors overseeing method development.
6. Biostatisticians supporting analytical projects.
7. Process Development Scientists applying PAT/QbD.
8. Research Associates in pharmaceutical and biotech industries.

Course Modules

Module 1: Foundations of Analytical Statistics and Regulation

- Review of core statistical concepts
- Understanding different types of errors and their impact on method development.
- Introduction to ICH Q2(R1), ICH Q14 (QbD), and USP general chapters.
- The transition from classical validation to the Method Lifecycle Management (MLCM) approach.
- Selecting appropriate statistical software and data visualization techniques.
- Case Study: Comparing two candidate analytical methods for a new drug product using Student's t-test and F-test for a final selection decision.

Module 2: Analytical Quality by Design (AQbD) and the ATP

- Defining the Analytical Target Profile (ATP) and Quality Attributes (QAs).
- Identifying and statistically ranking Critical Method Parameters (CMPs).
- Introduction to the Risk Assessment matrix for method development.
- Initial screening experiments using Plackett-Burman Design (PBD).
- Establishing the Reportable Value and its statistical implications.
- Case Study: Using an FMEA to identify high-risk chromatographic parameters and prioritizing them for DoE optimization.

Module 3: Fundamentals of Design of Experiments (DoE)

- Principles of Experimental Design and statistical efficiency.
- Implementing Full and Fractional Factorial Designs for parameter screening.
- Analyzing main effects and interaction effects using ANOVA and Pareto charts.
- Understanding lack-of-fit and pure error in statistical models.
- Statistical justification for reducing the number of runs.
- Case Study: A 2^4 Factorial Design to screen the effect of four variables on an HPLC assay's resolution and retention time.

Module 4: Response Surface Methodology (RSM)

- Optimizing Critical Method Parameters using Central Composite Design and Box-Behnken Design
- Generating response surface plots and contour plots for visualization.
- Identifying the Optimum Operating Conditions and desired sweet spot.
- Utilizing the Derringer's Desirability Function for multi-response optimization.
- Statistical criteria for verifying the Method Operable Design Region (MODR).
- Case Study: Application of a BBD to simultaneously optimize a dissolution test's rotation speed and solvent volume to meet multiple acceptance criteria.

Module 5: Statistical Assessment of Linearity and Range

- Advanced Linear Regression and assumptions checking
- Statistical assessment of working range and non-linearity.

- Calculating the Calibration Curve and statistical quality indicators
- Using Weighted Regression to handle non-constant variance.
- Establishing the statistical validity of the Intercept and Slope.
- Case Study: A linearity study for a complex API assay where weighted least squares regression is justified and applied due to non-constant variance at low concentrations.

Module 6: Determination of Limits (LOD & LOQ)

- Statistical approaches for determining the Limit of Detection (LOD)
- Statistical approaches for determining the Limit of Quantitation (LOQ)
- The use of Standard Deviation of the Response (?â) and the Slope (m) from the calibration curve.
- Confidence intervals for LOD and LOQ estimates.
- Statistical considerations for trace analysis and impurity testing.
- Case Study: Calculating and statistically justifying the LOQ for a critical cleaning validation residue method, focusing on the appropriate standard deviation selection.

Module 7: Advanced Precision and Accuracy Statistics

- Statistical difference between Repeatability, Intermediate Precision, and Reproducibility.
- Calculating Variance Components using ANOVA and nested designs.
- Determining the Trueness of the method using certified reference materials and statistical comparison.
- Using Confidence Intervals and Tolerance Intervals for acceptance criteria.
- The role of Statistical Process Control (SPC) in precision maintenance.
- Case Study: Applying Nested ANOVA to an intermediate precision study to statistically isolate and quantify the variance contribution of different analysts and instrument units.

Module 8: Statistical Assessment of Robustness

- Robustness definition as a statistical evaluation of method reliability under minor variations.
- Statistically analyzing data from a Robustness DoE.
- Calculating the Method Operable Design Region boundaries based on acceptance criteria.
- Using Prediction Intervals from the DoE model to confirm robustness.
- Statistical strategies for optimizing the method Control Strategy.
- Case Study: A fractional factorial DoE is performed for a robustness study, and statistical modeling is used to confirm the method remains within the ATP when mobile phase pH and flow rate are slightly varied.

Module 9: Measurement Uncertainty (MU) and ISO GUM

- Introduction to the Guide to the Expression of Uncertainty in Measurement framework.
- Identifying and statistically quantifying all uncertainty sources
- Calculating the Combined Standard Uncertainty (uc?Çï) using the Law of Propagation of Uncertainty.
- Determining and reporting the Expanded Uncertainty (U) with a specified Coverage Factor (k).
- Statistical relationship between MU, Validation Data, and Tolerance Limits.
- Case Study: Calculating the final Measurement Uncertainty for a titrimetric assay, combining uncertainties from calibration, purity of reference standard, and validation precision data.

Module 10: Statistical Quality Control (SQC) and Control Charts

- Fundamentals of Statistical Process Control (SPC) and its application in the lab.
- Developing and interpreting Shewhart Control Charts

- Setting statistically justified Control Limits and Warning Limits.
- Statistical rules for identifying Out-of-Control (OOC) conditions
- Using control charts for routine monitoring of System Suitability and long-term method stability.
- Case Study: Establishing an L-bar Control Chart for a critical reagent blank value and using it to monitor and statistically prevent the recurrence of systematic drift.

Module 11: Chemometrics and Multivariate Data Analysis (MVDA)

- Introduction to Multivariate Data Analysis for complex analytical data sets.
- Applying Principal Component Analysis for pattern recognition and outlier detection.
- Using Partial Least Squares regression for developing predictive models.
- Statistical validation of Chemometric Models
- Application in Near-Infrared (NIR) and Raman Spectroscopy method development.
- Case Study: Using PCA on spectral data collected during a method run to identify and statistically track a previously unknown co-eluting impurity, indicating a potential robustness failure.

Module 12: Statistical Data Analysis for Method Transfer and Comparison

- Designing robust Method Transfer Protocols with statistically sound acceptance criteria.
- Using Equivalence Testing to prove statistical comparability between labs.
- Statistical treatment of Outlier Data and justification for removal.
- Statistical techniques for comparing Inter-laboratory and Intra-laboratory results.
- Calculating and interpreting the Bias and Confidence Limits for method comparison.
- Case Study: Applying Equivalence Testing to compare the assay results from a transferring laboratory and a receiving laboratory to statistically confirm the method transfer success.

Module 1 3: Statistical Analysis of Stability Data

- Regression Analysis for Shelf-Life Estimation
- Statistical testing for pooling of batches in stability studies
- Calculating and interpreting the Confidence Interval for the Expiration Date.
- Statistical analysis of Forced Degradation study data for specificity confirmation.
- Using Time-to-Event analysis for certain stability endpoints.
- Case Study: Statistically analyzing 12 months of accelerated and long-term stability data for three commercial batches of a drug product to determine if the data can be pooled for a common shelf-life calculation.

Module 14: Risk-Based Method Lifecycle Management

- Statistical justification for Method Control Strategy
- Linking MODR and MU to the method Control Strategy.
- Using statistics to determine when Partial or Full Revalidation is necessary.
- Statistical techniques for Continuous Process Verification of analytical methods.
- Developing a statistically-justified Method Maintenance plan.
- Case Study: Applying DoE and MODR principles to statistically justify a wider operational range for an HPLC column temperature, thus reducing the need for revalidation after minor instrument variations.

Module 15: Review and Software Application

- Comprehensive review of the statistical roadmap from AQbD to MLCM.
- Advanced scripting and automation for recurring statistical tasks in R or Python.

- Reporting and effectively communicating complex statistical results to non-statisticians
- Statistical best practices for data integrity and audit trail.
- Final Q&A and Troubleshooting statistical challenges in real-world method data.
- Case Study: Participants individually analyze a provided method validation dataset in the statistical software, generating a final report including MU, MODR, and control chart recommendations.

Training Methodology

The course employs a highly interactive, practical, and hands-on methodology:

- Conceptual Learning.
- Case-Based Learning
- Practical Workshops
- Collaborative Group Projects.
- Data-Driven Focus.

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

Start Date	End Date	Location	Price
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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