Advanced Statistics for Pharmaceutical 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

The pharmaceutical industry operates under a mandate of precision, efficacy, and safety, governed by rigorous global regulatory standards. This is where Advanced Statistics transforms from a supporting function into a critical business accelerator. Drug development is inherently a process of managing uncertainty, from early-stage Drug Discovery and Process Validation to complex Confirmatory Clinical Trials and Real-World Evidence (RWE) generation. Professionals must master modern quantitative methods beyond basic descriptive statistics to extract maximum value and reliable inference from increasingly complex, high-dimensional datasets, including those generated from -omics and Personalized Medicine initiatives. The adoption of new methodologies like Bayesian Adaptive Design and Machine Learning is no longer optional; it is fundamental to accelerating time-to-market, optimizing Dose-Response Modeling, and ensuring Regulatory Compliance.

Advanced Statistics for Pharmaceutical Development Training Course is designed to equip biostatisticians, clinical scientists, and R&D leaders with the cutting-edge analytical toolkit required to drive data-driven decision-making throughout the pharmaceutical lifecycle. Participants will gain practical expertise in applying sophisticated statistical models including Mixed Models, Survival Analysis, and Design of Experiments (DoE) to critical areas such as Bioequivalence studies, Quality by Design (QbD), and Missing Data Imputation. By focusing on the Estimand framework and Sensitivity Analysis as mandated by regulatory bodies, this training ensures that all statistical conclusions are robust, reproducible, and defendable to health authorities, thereby reducing costly delays and strengthening the evidence base for new therapies.

Programme Curriculum

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Introduction

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Course Duration

10 days

Course Objectives

Upon completion, participants will be able to:

1. Master the application of the ICH E9 (R1) Estimand framework for defining the treatment effect in clinical trials.
2. Design and analyze Bayesian Adaptive Clinical Trials to improve efficiency and reduce sample size.
3. Perform robust Missing Data Imputation using advanced techniques like Multiple Imputation and sensitivity analysis.
4. Apply Design of Experiments (DoE), including Fractional Factorial and Response Surface Methodology, for QbD and Process Optimization.
5. Develop and validate advanced Pharmacokinetic/Pharmacodynamic (PK/PD) Models using Non-Linear Mixed Effects (NLME) modeling.
6. Execute and interpret Survival Analysis using the Cox Proportional Hazards Model with time-dependent covariates for oncology/longitudinal data.
7. Analyze and interpret Real-World Data (RWD) to generate Real-World Evidence (RWE) for regulatory submissions and post-market studies.
8. Implement Machine Learning (ML) models such as Random Forests and Deep Learning for Biomarker Identification and Patient Stratification.
9. Conduct rigorous statistical assessments for Biosimilarity and Bioequivalence using confidence interval approaches.
10. Utilize Generalized Linear Mixed Models (GLMMs) for analyzing complex Longitudinal Data and repeated measures.

11. Apply Meta-Analysis and Network Meta-Analysis (NMA) techniques for comparative effectiveness and evidence synthesis.
12. Establish and monitor Statistical Process Control (SPC) charts for Ongoing Process Verification (OPV) in manufacturing.
13. Effectively communicate complex statistical results and model assumptions to non-statistical stakeholders and regulatory agencies.

Target Audience

1. Biostatisticians and Statistical Programmers (Junior to Senior level).
2. Clinical Research Scientists and Clinical Data Managers.
3. R&D Scientists involved in formulation, manufacturing, and process development.
4. Regulatory Affairs Professionals who review and interact with statistical reports.
5. Clinical Pharmacologists and PK/PD Scientists.
6. Quality Assurance (QA) and Quality Control (QC) specialists.
7. Medical Affairs and Health Economics Outcomes Research (HEOR) professionals.
8. Project Leaders and Managers overseeing drug development teams.

Course Modules

Module 1: Statistical Principles & the Estimand Framework

- Review of core inferential statistics and hypothesis testing principles.
- The ICH E9(R1) Estimand framework.
- Strategy for handling intercurrent events
- The role of Sensitivity Analysis and its alignment with the estimand.
- Case Study: Developing a Target Estimand for an oncology trial where patients may switch to a new treatment upon progression.

Module 2: Advanced Clinical Trial Design and Power

- Statistical considerations for Superiority, Non-Inferiority, and Equivalence trials.
- Sample size re-estimation (SSR) and blinded interim analyses.
- Adaptive Design strategies.
- Multi-arm Multi-stage (MAMS) designs for increased efficiency.
- Case Study: Calculating power for a non-inferiority study and designing a two-stage adaptive trial for dose selection.

Module 3: Bayesian Methods in Drug Development

- Fundamentals of Bayesian Inference, prior specification, and posterior distribution.
- Introduction to Markov Chain Monte Carlo (MCMC) simulation.
- Application in Dose Escalation studies
- Bayesian methods for Adaptive Randomization and platform trials.
- Case Study: Using Bayesian methods to incorporate historical control data into a Phase II trial for a rare disease.

Module 4: Longitudinal and Repeated Measures Data

- Choosing the appropriate model.
- Linear Mixed-Effects Models (LMEM) for continuous outcomes.
- Generalized Linear Mixed Models for non-normal data

- Handling correlation structures, fixed vs. random effects, and model selection.
- Case Study: Analyzing patient pain scores collected weekly over a 12-week clinical trial using a LMEM.

Module 5: Survival and Time-to-Event Analysis

- Kaplan-Meier Curves and Log-Rank Test review.
- Cox Proportional Hazards Model for continuous and categorical predictors.
- Assessing and handling the Proportional Hazards Assumption violation.
- Advanced topics: Stratified Cox Models and Time-Dependent Covariates.
- Case Study: Modeling overall survival in a cancer trial and accounting for a biomarker whose level changes over time.

Module 6: Missing Data: Principles and Practice

- Mechanisms of Missing Data and their implications.
- Single Imputation methods and why they are generally discouraged.
- Multiple Imputation using methods like Multivariate Imputation by Chained Equations
- Regulatory expectations for Missing Data Sensitivity Analysis.
- Case Study: Implementing and comparing MI strategies versus a reference analysis for a quality-of-life endpoint with a high dropout rate.

Module 7: Bioequivalence and Biosimilarity

- Statistical criteria for Average Bioequivalence and the 80?êÆ125% rule.
- Handling highly variable drug products using Scaled Average Bioequivalence
- Tiered approaches to establishing Biosimilarity using Equivalence Testing.
- Non-parametric methods and reference-scaled average bioequivalence.
- Case Study: Assessing the bioequivalence of a new generic formulation of a highly variable drug product.

Module 8: Design of Experiments (DoE) for Formulation

- Fundamentals of Factorial Designs and screening experiments.
- Fractional Factorial designs for efficiently identifying critical factors.
- Response Surface Methodology for optimal process mapping.
- Using DoE to support Quality by Design and validation efforts.
- Case Study: Utilizing DoE to optimize the concentration of three excipients to maximize drug dissolution rate.

Module 9: Statistical Process Control (SPC) in Manufacturing

- Principles of Process Validation and Ongoing Process Verification
- Selection and interpretation of Control Charts
- Calculating Process Capability indices for critical quality attributes
- Handling non-normal data and batch-to-batch variation in SPC.
- Case Study: Setting up a CUSUM chart to monitor a critical tablet hardness CQA for drift over multiple production batches.

Module 10: Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling

- Introduction to Non-Linear Mixed-Effects modeling
- Modeling single and multiple-dose PK data.

- Integrating PK data with PD responses for Dose-Response characterization.
- Population PK/PD modeling for informing dosing in special populations.
- Case Study: Developing a population PK model to determine optimal dosing for pediatric patients based on limited sampling.

Module 11: Real-World Evidence (RWE) and Observational Data

- Sources of RWD and their statistical challenges
- Propensity Score Matching and Inverse Probability of Treatment Weighting for causal inference.
- Statistical methods for Comparative Effectiveness Research
- Addressing bias and heterogeneity in observational studies.
- Case Study: Using PSM to compare the safety profile of a newly marketed drug against a comparator using electronic health record data.

Module 12: Machine Learning for Drug Discovery and Trials

- Introduction to Supervised and Unsupervised Learning in pharma.
- Classification and Regression with techniques like Random Forests and Support Vector Machines
- Application in Biomarker Identification and predicting clinical trial success/failure.
- Model validation, cross-validation, and addressing data imbalance.
- Case Study: Building a Random Forest classifier to predict patient response to an experimental therapy based on genomic and clinical features.

Module 13: Statistical Genetics and High-Dimensional Data

- Analysis of Genomic and Transcriptomic data
- Handling the Multiple Testing Problem in high-dimensional settings.
- Introduction to Principal Component Analysis (PCA) and other dimensionality reduction techniques.
- Statistical methods for integrating multi-omics data for Personalized Medicine.
- Case Study: Applying PCA to gene expression data to identify patient clusters for a targeted therapy.

Module 14: Meta-Analysis and Synthesis of Evidence

- Statistical models for Fixed-Effect and Random-Effects meta-analysis.
- Assessing and quantifying Heterogeneity
- Introduction to Network Meta-Analysis for indirect comparisons.
- Funnel plots and statistical methods for detecting Publication Bias.
- Case Study: Conducting a meta-analysis of five Phase III trials to estimate the pooled effect size of a new drug versus placebo.

Module 15: Regulatory Reporting and Communication

- Structure and content of the Statistical Analysis Plan and Clinical Study Report
- Best practices for data visualization
- Translating complex statistical findings into clear, defensible language for Non-Statisticians
- Addressing common statistical questions raised by the FDA and EMA during review.
- Case Study: Preparing a summary memo of key primary and sensitivity analyses for a regulatory submission meeting.

Training Methodology

The course employs a blended and highly interactive approach designed for maximum knowledge retention and practical skill development:

- Interactive Lectures.
- Hands-on Software Labs.
- In-Depth Case Studies.
- Group Problem-Solving.
- Expert Q&A Sessions.

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

Start Date	End Date	Location	Price
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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