Advanced ADME/PK/PD Modeling and Simulation 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

Advanced ADME/PK/PD Modeling and Simulation Training Course is meticulously designed to equip drug development professionals with a mastery of Model-Informed Drug Development (MIDD) principles, leveraging the full power of ADME/PK/PD modeling and simulation. In the modern pharmaceutical landscape, the shift from empirical experimentation to quantitative pharmacology is critical for accelerating discovery, optimizing clinical trial design, and ultimately reducing the staggering costs and high attrition rates associated with drug candidates. Participants will move beyond foundational concepts to tackle complex, real-world drug development challenges, including Target-Mediated Drug Disposition (TMDD), intricate Drug-Drug Interaction (DDI) predictions, and the use of Physiologically-Based Pharmacokinetic (PBPK) modeling for special populations. The program emphasizes a data-driven, translational approach, ensuring attendees can rigorously apply pharmacometrics techniques to influence key strategic decisions from lead optimization through regulatory submission.

The core focus is on building practical, hands-on expertise in developing, validating, and critically interpreting non-linear mixed-effects models (NLME) and PBPK models using industry-leading software. By integrating in vitro-in vivo extrapolation (IVIVE) and systems biology approaches, professionals will gain the skills to generate robust quantitative predictions of human pharmacokinetics and pharmacodynamics, guiding optimal dose selection and regimen design for diverse patient groups. This training is essential for those committed to de-risking their pipeline, streamlining regulatory interactions, and driving scientific innovation by transforming raw data into powerful, predictive insights that accelerate the delivery of safe and effective medicines.

Programme Curriculum

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Course Duration

10 days

Course Objectives

Upon completion of this course, participants will be able to:

1. Master the application of Model-Informed Drug Development (MIDD) to de-risk late-stage attrition.
2. Develop and critically evaluate Physiologically-Based Pharmacokinetic (PBPK) models for complex drug candidates.
3. Implement Non-Linear Mixed-Effects (NLME) modeling for robust Population PK (PopPK) analysis in diverse patient cohorts.
4. Quantitatively predict and mitigate clinical Drug-Drug Interactions (DDI) using PBPK and mechanistic models.
5. Design and interpret models for Target-Mediated Drug Disposition (TMDD) and complex biotherapeutic kinetics.
6. Apply advanced statistical methods for covariate analysis to explain inter-individual variability in drug response.
7. Integrate In Vitro-In Vivo Extrapolation (IVIVE) and Quantitative Systems Pharmacology (QSP) principles into translational models.
8. Accurately predict First-in-Human (FIH) dosing and optimal regimens using preclinical data and modeling.
9. Perform Clinical Trial Simulation (CTS) for adaptive trial design and robust phase II/III planning.
10. Conduct rigorous model validation, sensitivity analysis, and uncertainty quantification to ensure regulatory readiness.

11. Develop Exposure-Response (E-R) models to define the therapeutic window and optimal target engagement.
12. Generate model-based extrapolations for Special Populations
13. Prepare and defend Pharmacometrics (PMx) reports and model evidence for FDA/EMA regulatory submissions.

Target Audience

1. Clinical Pharmacologists and Scientists.
2. PK/PD Scientists and Pharmacometricians.
3. Toxicologists and DMPK Researchers.
4. Regulatory Affairs Professionals.
5. Biostatisticians and Data Scientists.
6. Pharmaceutical and Biotech Project Managers.
7. Postdoctoral Researchers and PhD Candidates.
8. Formulation and Drug Delivery Scientist.

Course Modules

1. Advanced Pharmacokinetic Principles

- Review of non-linear PK.
- Understanding and modeling of high-throughput in vitro ADME screens
- Quantitative description of tissue distribution and plasma protein/tissue binding models.
- Advanced compartmental modeling.
- Case Study: Modeling the non-linear clearance of a novel small molecule hepatic uptake transporter substrate.

2. Mechanistic PBPK Modeling Fundamentals

- Constructing the physiological system.
- Integrating drug-specific parameters.
- Developing tissue-specific binding models and understanding their impact on distribution.
- Using PBPK for IVIVE and predicting human in vivo clearance from in vitro data.
- Case Study: Building a PBPK model for a lipophilic drug to predict brain and liver tissue exposure.

3. PBPK Modeling for Oral Absorption

- The Advanced Compartmental Absorption and Transit (ACAT) model and its application.
- Modeling dissolution, precipitation, and complex formulation effects
- Predicting food effects and the impact of gastrointestinal pH changes.
- Integrating PBPK with QSP to model gut microbiome-mediated metabolism.
- Case Study: Using PBPK to justify a biowaiver for a new drug formulation based on dissolution data.

4. Advanced Drug-Drug Interaction (DDI) Modeling

- Mechanistic modeling of Cytochrome P450 (CYP) inhibition and induction.
- Transporter-mediated DDIs and incorporating in vitro inhibition data.
- Developing a PBPK-DDI model to predict the magnitude of clinical interaction.
- Regulatory expectations (FDA/EMA) for DDI study design and modeling reports.
- Case Study: Predicting the clinical DDI between a potent CYP3A4 inhibitor and a victim drug with narrow therapeutic index.

5. Population Pharmacokinetics (PopPK) Theory

- Statistical principles of NLME modeling
- Quantifying and differentiating between inter-individual and intra-individual variability.
- Model building strategy.
- Introduction to NONMEM/Monolix/Phoenix WinNonlin software environment and coding.
- Case Study: Building a PopPK model for a Phase I dataset to characterize PK variability in healthy volunteers.

6. PopPK Covariate Modeling and Interpretation

- Selecting and testing clinically relevant covariates
- Applying the Generalized Additive Model (GAM) for non-linear covariate relationships.
- Graphical methods for model evaluation.
- Addressing model misspecification and handling sparse or unbalanced data structures.
- Case Study: Identifying significant covariates that drive PK variability in an oncology patient population.

7. Introduction to Pharmacodynamics (PD) Modeling

- Basic PD models.
- Direct, indirect, and turnover models for capturing delayed and non-equilibrium effects.
- Modeling receptor occupancy and the link between drug concentration and target effect.
- Integrating biomarkers into PK/PD models.
- Case Study: Developing an indirect response model to fit a time-course of an effect in response to a drug.

8. Advanced PK/PD and Translational Modeling

- Connecting PopPK to PopPD through the Exposure-Response (E-R) relationship.
- Modeling Target-Mediated Drug Disposition (TMDD) for biologics and antibodies.
- Translational PK/PD: Scaling preclinical E-R to predict human efficacy and safety.
- Applying models to characterize the time course of tolerance and rebound effects.
- Case Study: Building a TMDD model for a monoclonal antibody to predict saturation kinetics in patients.

9. Clinical Trial Simulation (CTS) and Optimal Design

- Principles of Stochastic Simulation for predicting trial outcomes and power.
- Using simulation to compare different dosing regimens and study designs
- Applying Optimal Design methods to maximize information from a trial.
- Designing Adaptive Clinical Trials based on interim model predictions.
- Case Study: Simulating a Phase III clinical trial to justify a lower, less frequent dosing regimen based on predicted efficacy and variability.

10. Modeling in Special Populations

- Developing Pediatric Extrapolation Models using PBPK and allometric scaling.
- Modeling the impact of Renal and Hepatic Impairment on PK/PD parameters.
- Dose adjustment strategies based on model predictions for elderly and comorbid patients.
- Addressing Ethnicity and Genetic Polymorphism in PK through modeling.
- Case Study: Utilizing a PBPK model to predict the necessary dose reduction for a drug in patients with severe renal impairment.

11. Advanced Topics in Biologics and Novel Modalities

- Modeling the PK/PD of Antibody-Drug Conjugates (ADCs) and their components.
- Pharmacometric approaches for Cell and Gene Therapy kinetics and engraftment.
- Challenges in modeling Peptide and Oligonucleotide disposition.
- Modeling the complex absorption and distribution of subcutaneous dosing.
- Case Study: Developing a multi-compartment model for an ADC, tracking parent drug, released payload, and target dynamics.

12. Model Validation and Uncertainty Quantification

- Methods for Internal and External Model Validation
- Performing Sensitivity Analysis to identify key driving parameters.
- Techniques for Uncertainty Quantification (UQ) and building Confidence Intervals.
- Model qualification and best practices for model reporting
- Case Study: Conducting a comprehensive bootstrap analysis on a PopPK model to robustly quantify parameter uncertainty and stability.

13. Regulatory Application and Communication

- Understanding FDA/EMA/PMDA guidance on Model-Informed Drug Development
- Structuring and writing a persuasive Pharmacometrics and PBPK regulatory submission report.
- Preparing for regulatory meetings and defending model-based conclusions.
- The role of modeling in label claims, warnings, and patient information.
- Case Study: Reviewing and critiquing a successful regulatory submission where PBPK models replaced a clinical DDI study.

14. Quantitative Systems Pharmacology (QSP) Introduction

- Principles of QSP: Integrating molecular, cellular, and organ-level data.
- The use of QSP models to explore novel drug targets and disease pathways.
- Connecting PK/PD to QSP: Bridging drug exposure to disease progression.
- Software and resources for building and simulating QSP models.
- Case Study: Using a QSP model to predict the efficacy of a new anti-inflammatory drug based on its mechanism of action and known disease pathology.

15. Automation and Data Science in Pharmacometrics

- R and Python for automated data preparation, analysis, and visualization.
- Developing reproducible Pharmacometrics workflows and reporting
- Introduction to Machine Learning (ML) for predictive ADME and PK property estimation.
- Best practices for data management and database integration in PK/PD studies.
- Case Study: Building an R Shiny application to automate Visual Predictive Checks (VPCs) and simulation reports for internal review.

Training Methodology

The course employs an **Active Learning** approach, blending high-level theory with extensive hands-on application.

- Lectures.
- Workshops.

- Case Studies.
- Group Project.

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

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$12,000

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