Pre-Clinical Drug Development and Toxicology 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

Pre-Clinical Drug Development and Toxicology Training Course is designed to equip participants with a rigorous, industry?Çærelevant foundation in the discovery, safety evaluation, and translational strategies required before a drug enters human trials. This immersive program combines mechanistic science, regulatory awareness, and practical case studies to deliver a robust, outcome?Çæoriented learning experience. Through state?Çæof?Çæthe?Çæart tools, in silico modeling, in vitro and in vivo toxicology, and integrated pharmacokinetic/pharmacodynamic strategies, participants will graduate with actionable competencies to advance novel compounds toward clinical readiness.

By aligning with current regulatory expectations and leveraging real?Çæworld case studies, the curriculum fosters critical thinking and decision-making capacity across preclinical pipelines. Learners will gain fluency in safety risk assessment, lead optimization, dose selection, biomarker integration, and translational toxicology skills increasingly in demand in pharma, biotech, contract research organizations, and academia. This course emphasizes hands?Çæon application, problem-solving, and exposure to cutting-edge approaches such as computational toxicology and quantitative in vitro-to-in vivo extrapolation

Programme Curriculum

Pre-Clinical Drug Development and Toxicology Training Course

Introduction

Pre-Clinical Drug Development and Toxicology Training Course provides a comprehensive overview of the **pre-clinical drug development** and **toxicology** process, a critical phase that bridges **drug discovery** with **clinical trials**. Participants will gain an in-depth understanding of the **regulatory requirements**, **study design**, and

data analysis essential for advancing a compound toward **first-in-human** studies. The curriculum is designed to equip aspiring and current professionals with the skills to navigate the complex landscape of **non-clinical safety evaluation**, ensuring the **safety** and **efficacy** of novel therapeutics. Through modules on **pharmacology**, **pharmacokinetics**, and **toxicology testing**, this course demystifies the scientific and regulatory frameworks mandated by agencies like the **FDA** and **EMA**.

The program delves into the latest trends and technologies shaping **pre-clinical research**, including **in silico modeling**, **AI-powered drug discovery**, and the use of **patient-derived organoids**. Participants will learn to apply **Good Laboratory Practice (GLP)** standards and interpret complex data from **in vitro** and **in vivo** studies. By the end of the course, attendees will be proficient in drafting key regulatory documents, such as the **Investigational New Drug (IND)** application, and will be prepared to contribute to successful **drug development programs**. This training is a crucial step for anyone seeking to accelerate their career in the dynamic and highly regulated field of **biopharmaceutical research**.

Course Duration

10 days

Course Objectives

1. Evaluate the role of non-clinical safety assessment in the overall drug development lifecycle.
2. Design and implement robust pre-clinical study protocols that adhere to Good Laboratory Practice (GLP).
3. Analyze and interpret data from pharmacokinetics (PK) and pharmacodynamics (PD) studies.
4. Identify and characterize potential drug toxicity and adverse effects through various toxicology assays.
5. Master the principles of in vitro and in vivo study design, including dose range-finding and species selection.
6. Apply the ICH guidelines and other regulatory frameworks for submitting Investigational New Drug (IND) applications.
7. Utilize computational toxicology and in silico modeling to predict drug properties and safety profiles.
8. Understand the process of biologics and biosimilars development and their specific pre-clinical requirements.
9. Develop effective biomarker strategies for monitoring efficacy and toxicity in pre-clinical studies.
10. Assess the risk-benefit profile of a drug candidate before proceeding to clinical trials.
11. Prepare high-quality Common Technical Document (CTD) sections for regulatory submissions.
12. Explore the latest technological innovations in pre-clinical imaging and data analytics.
13. Communicate effectively with cross-functional teams, regulatory agencies, and Contract Research Organizations (CROs).

Target Audience

- Pharmacologists and toxicologists seeking to enhance their knowledge of pre-clinical development.
- Pharmaceutical scientists and research associates involved in drug discovery.
- Regulatory affairs specialists and quality assurance professionals in the biotech industry.
- Medical writers and project managers who need a deeper understanding of non-clinical data.
- Students and academics pursuing careers in pharmaceutical R&D.
- Biotech startup founders and investors requiring insights into early-stage drug programs.
- Clinicians and clinical researchers interested in the foundational science behind clinical trials.
- Biomedical engineers and chemists transitioning into pre-clinical research roles.

Course Outline

Module 1: Introduction to Pre-Clinical Drug Development

- Overview of the drug development pipeline.
- The role of pre-clinical studies as a gateway to clinical trials.
- Key stakeholders and their responsibilities.
- Understanding the Investigational New Drug (IND) application.
- **Case Study:** The Thalidomide Tragedy.

Module 2: Pharmacology & Pharmacodynamics

- Target identification and validation.
- Mechanism of action (MOA) and efficacy studies.
- Dose-response relationships and the therapeutic window.
- Pharmacodynamics (PD) models and biomarker discovery.
- **Case Study:** The Development of a Novel Cancer Immunotherapy.

Module 3: Pharmacokinetics (PK) & ADME

- Principles of Absorption, Distribution, Metabolism, and Excretion (ADME).
- In vitro PK assays and high-throughput screening.
- Species selection for non-rodent and rodent studies.
- PK modeling and allometric scaling.
- **Case Study:** PK Profile of a Small Molecule Drug.

Module 4: General Toxicology & Safety Pharmacology

- Acute, sub-chronic, and chronic toxicity studies.
- Maximum tolerated dose (MTD) and No Observed Adverse Effect Level (NOAEL).
- Safety pharmacology studies (cardiovascular, respiratory, and CNS).
- Target organ toxicity identification.
- **Case Study:** A Drug with Off-Target Cardiovascular Effects.

Module 5: Genotoxicity & Carcinogenicity

- Genetic toxicology testing
- In vivo genotoxicity assays and their relevance.
- Principles of carcinogenicity studies and their duration.
- Understanding regulatory requirements for these studies.
- **Case Study:** Addressing a Positive Genotoxicity Signal.

Module 6: Reproductive & Developmental Toxicology

- Testing for **fertility** and **early embryonic development**.
- Embryo-fetal development studies.
- Pre-natal and post-natal development assessments.
- Importance of gender-specific toxicity data.
- **Case Study:** A Drug's Impact on Developmental Toxicity.

Module 7: In Silico & Computational Toxicology

- Introduction to computational toxicology.
- Quantitative Structure-Activity Relationships (QSAR).

- AI-driven drug discovery and virtual screening.
- Prediction of ADME and toxicity using computational models.
- **Case Study:** Using AI to Predict Drug Hepatotoxicity.

Module 8: Biologics & Novel Modalities

- Pre-clinical development of antibodies, cell therapies, and gene therapies.
- Challenges in immunogenicity and biosimilarity testing.
- The use of humanized animal models.
- Regulatory considerations for advanced therapeutic medicinal products (ATMPs).
- **Case Study:** The Pre-Clinical Path of a Monoclonal Antibody**.**

Module 9: Good Laboratory Practice (GLP)

- Fundamentals of GLP and its regulatory foundation.
- Documentation, Standard Operating Procedures (SOPs), and audits.
- Quality assurance in pre-clinical studies.
- Data integrity and reproducibility.
- **Case Study:** An FDA Audit and a GLP Violation.

Module 10: Regulatory Submission & IND Filing

- The structure of the Common Technical Document (CTD).
- Preparing the non-clinical sections for an IND.
- Risk assessment and benefit-risk analysis.
- Strategies for effective regulatory engagement.
- **Case Study:** Navigating an FDA Pre-IND Meeting.

Module 11: Toxicology in a Real-World Setting

- The role of contract research organizations (CROs).
- Outsourcing strategies and vendor management.
- Project management for pre-clinical programs.
- Cost-effectiveness and timeline management.
- **Case Study:** Choosing the Right CRO for a Complex Toxicology Program.

Module 12: Biomarkers & Translational Toxicology

- Biomarker discovery and validation.
- Translational biomarkers bridging pre-clinical and clinical stages.
- Toxicogenomics and toxicoproteomics.
- The use of omics data to predict toxicity.
- **Case Study:** A Novel Biomarker for Kidney Toxicity.

Module 13: Advanced Topics & Emerging Trends

- Organ-on-a-Chip technologies.
- Real-world evidence in toxicology.
- Personalized medicine and its impact on pre-clinical research.
- Next-generation sequencing and its role in safety assessment.
- **Case Study:** Integrating Organ-on-a-Chip Technology**.**

Module 14: Special Toxicology Considerations

- Phototoxicity and dermal toxicity studies.
- Immunotoxicity and hypersensitivity reactions.
- Drug-drug interactions and their toxicological implications.
- Toxicology of excipients and impurities.
- **Case Study:** Investigating a Phototoxicity Signal**.**

Module 15: Professional Development

- Careers in pre-clinical development and toxicology.
- Networking strategies in the pharma and biotech industries.
- Effective communication of scientific findings.
- Ethical considerations in animal research.
- **Case Study:** A Career Transition from Academia to Industry**.**.

Training Methodology

The course employs a blended learning approach that combines theoretical knowledge with practical, hands-on application. This includes:

- Interactive Lectures.
- Case Studies & Workshops.
- Group Discussions: Fostering peer-to-peer learning and problem-solving.
- Regulatory Document Analysis.
- Practical Demonstrations.

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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