Advanced Toxicology and Safety Pharmacology 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 escalating complexity of New Chemical Entities (NCEs) and biologics in the pharmaceutical pipeline necessitates a paradigm shift in preclinical safety assessment. Traditional toxicology models, while foundational, are being rapidly augmented and in some cases, replaced by advanced methodologies. This includes a heavy reliance on Computational Toxicology, particularly Quantitative Knowledge-Activity Relationships (QKARs), and sophisticated In Vitro Assays that align with the 3Rs principles. Mastering this advanced domain requires a deep understanding of mechanistic toxicology, the application of systems biology for adverse effect prediction, and the seamless integration of safety pharmacology studies as outlined in ICH S7A and S7B guidelines to de-risk drug candidates and accelerate the transition from preclinical discovery to successful First-in-Human (FIH) clinical trials.

Advanced Toxicology and Safety Pharmacology Training Course is engineered to bridge the knowledge gap between established toxicological principles and the cutting-edge technologies driving modern drug safety and risk assessment. Participants will gain expertise in designing integrated Investigational New Drug (IND)-enabling safety packages, interpreting complex multi-omics data, and deploying novel biomarkers for early detection of organ-specific toxicities, such as drug-induced liver injury (DILI) and cardiotoxicity. By emphasizing regulatory strategy, Good Laboratory Practice (GLP) compliance, and the critical role of Translational Safety, the course ensures professionals can perform evidence-based toxicology and provide definitive, high-impact safety decisions that are crucial for successful product development across the pharmaceutical and chemical industries.

Programme Curriculum

Advanced Toxicology and Safety Pharmacology Training Course

Introduction

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Course Duration

10 days

Course Objectives

Upon completion, participants will be able to:

1. Apply current ICH S7A/S7B Guidelines to design a comprehensive core battery of safety pharmacology studies.
2. Critically evaluate and implement In Vitro Cardiotoxicity Assays, including the hERG and ion channel assessments.
3. Design and interpret studies using Physiologically Based Pharmacokinetic modeling for Toxicokinetics and dose selection.
4. Master the application of High-Throughput Screening and In Silico Methods for early toxicity prediction.
5. Utilize Systems Biology and Toxicogenomics to elucidate the Molecular Mechanisms of Toxicity
6. Perform comprehensive Drug-Induced Liver Injury risk assessment using advanced biomarkers and mechanistic data.
7. Integrate Safety Pharmacology and General Toxicology assessments for efficiency and resource reduction.
8. Develop strategies for assessing Immunotoxicity and Immunosafety of NCEs and biologics.
9. Apply Next-Generation Risk Assessment (NGRA) strategies beyond traditional animal models
10. Navigate Global Regulatory Affairs requirements for preclinical safety reporting
11. Implement quality assurance and adherence to Good Laboratory Practice (GLP) and best practices.
12. Identify and mitigate risks associated with Reproductive and Developmental Toxicology
13. Leverage Computational Toxicology (QKARs) for robust prediction of adverse drug reactions

Target Audience

1. Toxicologists and Safety Scientists
2. Safety Pharmacologists and Cardiovascular Safety Experts
3. Drug Metabolism and Pharmacokinetics (DMPK) Scientists
4. Regulatory Affairs Specialists focused on preclinical data
5. Preclinical Research Managers and Study Directors
6. Bioanalytical and Biomarker Scientists
7. Senior Researchers in Pharmaceutical and Chemical R&D
8. Postdoctoral Researchers and Advanced Masters Students in related disciplines

Course Modules

Module 1: Foundations of Advanced Mechanistic Toxicology

- Principles of ADME and clearance pathways in toxicology.
- Advanced Toxicokinetics.
- Mechanisms of cellular injury and repair
- Role of Phase I and Phase II metabolism in bioactivation and toxicity.
- Case Study: The mechanism of acetaminophen-induced DILI and the role of CYP450 enzymes.

Module 2: Regulatory Toxicology and Global Harmonization

- Detailed review of ICH M3(R2) and country-specific regulatory requirements
- Design and execution of IND-Enabling General Toxicity Studies
- Mastering the requirements and documentation for Good Laboratory Practice
- Strategies for waiver requests and justifications for non-standard studies.
- Case Study: Analyzing a successful/failed IND application due to gaps in regulatory toxicology data.

Module 3: Advanced Safety Pharmacology

- In-depth review of ICH S7A and S7B requirements.
- CVS Core Battery.
- Functional Observation Battery (FOB) and automated behavior assessment.
- Respiratory Core Battery.
- Case Study: Investigating a drug withdrawn due to QT prolongation and the role of hERG testing.

Module 4: Cardiotoxicity and Ion Channel Safety

- Non-hERG ion channels and their contribution to arrhythmia risk.
- Advanced In Vitro Cardiotoxicity models.
- Translating preclinical CVS findings to clinical risk
- Role of biomarkers in preclinical injury detection.
- Case Study: Designing an integrated CVS safety package for a novel anti-cancer agent targeting kinase signaling.

Module 5: Computational and Predictive Toxicology

- Fundamentals of Quantitative Structure-Activity Relationship modeling.
- Introduction to Quantitative Knowledge-Activity Relationship approaches.
- Utilizing Machine Learning and Deep Learning for toxicity endpoint prediction.
- The use of public databases in read-across.
- Case Study: Employing QSAR tools to predict genotoxicity for a chemical series.

Module 6: Genotoxicity and Carcinogenicity Assessment

- The Genetic Toxicology Core Battery
- Understanding the transition from Genotoxicity to Carcinogenicity risk.
- Alternatives to the 2-year rodent bioassay.
- Epigenetic mechanisms in carcinogenesis and their assessment.
- Case Study: Resolving a positive in vitro genotoxicity result using mechanistic follow-up studies.

Module 7: Drug-Induced Liver Injury (DILI) Assessment

- Mechanistic basis of Hepatotoxicity.
- Advanced In Vitro Hepatocyte models
- Novel and translational DILI Biomarkers
- Strategies for predicting and managing clinical DILI risk
- Case Study: Analyzing a clinical DILI signal and tracing its origin back to preclinical mechanistic findings.

Module 8: Nephrotoxicity and Biomarker Discovery

- Mechanisms of Acute Kidney Injury and chronic nephrotoxicity.
- Validation and utilization of Translational Biomarkers for renal injury
- In Vitro models for renal assessment
- Combining renal injury biomarkers with functional assessments
- Case Study: Using a panel of novel biomarkers to detect early renal injury in a repeat-dose rat study.

Module 9: Immunotoxicology and Biologics Safety

- Assessing the immunomodulatory potential of NCEs and biologics.
- Strategies for evaluating immunotoxicity
- Safety assessment for Cell and Gene Therapies
- Testing for Hypersensitivity and anaphylactoid reactions.
- Case Study: Review of the TGN1412 clinical trial and the regulatory shift in assessing Cytokine Storm risk.

Module 10: Reproductive and Developmental Toxicology (DART)

- Regulatory requirements for Reproductive and Developmental Toxicity testing.
- Detailed review of Segment I, II, and III study designs and endpoints.
- Identification and assessment of potential Endocrine Disrupting Chemicals.
- Juvenile Toxicology study design and specific considerations.
- Case Study: Evaluating the preclinical data that led to the Thalidomide disaster and modern prevention strategies.

Module 11: Bioanalytical Methods and Biomarkers

- Integration of Pharmacokinetics and Pharmacodynamics data into safety studies.
- Advanced Omics Technologies for MoT elucidation.
- Criteria for the selection, qualification, and validation of novel Biomarkers.
- Methodology for measuring drug and metabolite concentrations in various matrices.
- Case Study: Utilizing a transcriptomic signature to predict the likelihood of an organ toxicity.

Module 12: Next-Generation Safety Assessment

- Global push for the 3Rs in safety testing.
- Adoption of New Approach Methodologies and Organ-on-a-Chip models.
- Role of High-Content Imaging (HCI) and Automated Microscopy in in vitro toxicology.
- Developing read-across and in vitro to in vivo extrapolation models.
- Case Study: Comparing the predictive value of a microphysiological system for DILI against traditional in vivo models.

Module 13: Non-Clinical Safety Report Writing and Submission

- Structuring and authoring the Non-Clinical Written and Tabulated Summaries
- Techniques for clear and compelling Risk Characterization and safety margin justification.
- Responding to regulatory agency queries
- The role of the toxicologist in early clinical trial monitoring and safety review.
- Case Study: Drafting the core safety summary for an NCE based on a full preclinical dataset.

Module 14: Safety Assessment of Biologics and Advanced Therapies

- Unique safety challenges and regulatory considerations for biologics
- Specialized non-rodent species selection for biologic studies.
- Assessing Immunogenicity and their safety impact.
- Toxicology of novel modalities like Oligonucleotides and CRISPR-based therapies.
- Case Study: Designing the non-clinical safety package for a first-in-class monoclonal antibody.

Module 15: Post-Marketing Safety and Pharmacovigilance Interface

- Understanding the transition of safety data to Pharmacovigilance.
- Preclinical data's role in interpreting Adverse Drug Reactions post-approval.
- Principles of Signal Detection and Signal Management in the clinical phase.
- Developing and implementing a Risk Management Plan.
- Case Study: Re-evaluating the non-clinical data for a drug that received a Black Box Warning post-marketing.

Training Methodology

The course employs an intensive, blended-learning approach to maximize knowledge retention and practical skill development:

1. Expert-Led Lectures.
2. Case Study Analysis.
3. Hands-on Workshops
4. Group Projects.
5. Q&A/Panel Discussions.

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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