Non-Clinical Safety Assessment of Novel Therapeutics 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

Non-Clinical Safety Assessment of Novel Therapeutics Training Course provides a comprehensive understanding of the critical processes involved in evaluating the safety of new drug candidates before clinical trials. In the ever-evolving landscape of pharmaceutical development, the preclinical phase is vital for identifying potential risks, ensuring patient safety, and complying with regulatory guidelines. This course emphasizes the integration of Good Laboratory Practices (GLP), toxicology testing, and pharmacology principles to evaluate the safety of novel therapeutics. Participants will learn to design, interpret, and apply non-clinical safety studies in the context of biopharmaceutical innovations and regulatory frameworks.

Equipped with in-depth case studies, industry insights, and expert-led methodologies, this training program is designed to help professionals in the pharmaceutical and biotech sectors stay ahead of trends and best practices. With a focus on innovative safety assessment approaches, participants will understand how to conduct toxicology assessments, analyze preclinical data, and navigate regulatory submissions for drug approval. The course blends theoretical concepts with practical, real-world applications, helping learners build the expertise needed to manage safety assessments effectively.

Programme Curriculum

Non-Clinical Safety Assessment of Novel Therapeutics Training Course

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Course Objectives

1. Understand the fundamentals of non-clinical safety assessment for novel therapeutics, focusing on toxicology, pharmacology, and GLP compliance.
2. Gain expertise in designing and interpreting preclinical safety studies for drug candidates in biotechnology and pharmaceutical industries.
3. Explore key toxicological principles, including acute toxicity, chronic toxicity, genotoxicity, and carcinogenicity testing.
4. Evaluate the role of non-clinical safety assessments in supporting regulatory approvals and ensuring patient safety.
5. Identify safety biomarkers and their application in the preclinical safety testing of novel therapeutics.
6. Master risk assessment strategies for evaluating the safety profile of new drug candidates.
7. Understand the regulatory guidelines set by agencies such as FDA, EMA, and ICH for non-clinical safety assessments.
8. Examine the role of animal models and in vitro assays in assessing therapeutic safety.
9. Learn the best practices for managing preclinical study data, including data analysis, reporting, and presentation.
10. Recognize the importance of safety pharmacology in understanding the cardiovascular, respiratory, and central nervous system effects of therapeutics.
11. Analyze case studies to understand real-world applications of non-clinical safety assessments in drug development.
12. Develop strategies for integrating non-clinical safety data into clinical trial designs to ensure a smooth transition from preclinical to clinical phases.
13. Implement advanced tools and technologies for safety assessment, including predictive toxicology and biomarker analysis.

Target Audience

1. Pharmaceutical industry professionals.
2. Biotech companies.
3. Toxicologists, safety officers, and regulatory affairs specialists.
4. Clinical research professionals.
5. Quality control and assurance managers in pharmaceutical and biotechnology sectors.
6. Research and development (R&D) teams.

7. Professionals working with biomarkers, pharmacology, and preclinical toxicology.
8. Regulatory affairs professionals.

Course Modules

Introduction to Non-Clinical Safety Assessment

- Overview of non-clinical safety testing
- Importance in drug development
- Regulatory frameworks (FDA, EMA, ICH)
- Key roles in non-clinical safety
- Case studies: Future trends in safety assessment

Fundamentals of Toxicology

- Types of toxicology studies
- Acute vs. chronic toxicity
- Genotoxicity and carcinogenicity
- Toxicokinetics
- Case studies of toxicology failures

Pharmacology and Safety Pharmacology

- Principles of pharmacology in safety
- Safety pharmacology testing (CNS, cardiovascular)
- Regulatory requirements
- Safety signals in pharmacology studies
- Case studies: Real-life examples of pharmacology issues

Preclinical Study Design

- Principles of study design
- Selection of animal models
- Statistical methods in toxicology studies
- Dosage and administration in preclinical trials
- Case study: designing a preclinical toxicology study

Biomarkers in Safety Assessment

- What are biomarkers?
- Types of safety biomarkers
- Role in toxicology testing
- Regulatory perspectives on biomarkers
- Case studies of biomarker usage

Risk Assessment Methodologies

- Introduction to risk assessment
- Qualitative and quantitative methods
- Safety margin calculations
- Decision-making in safety assessment
- Case study: risk assessment of a new therapeutic

Regulatory Requirements for Non-Clinical Safety

- ICH guidelines for non-clinical studies
- FDA and EMA safety requirements
- GLP standards in safety testing
- Reporting standards for non-clinical studies
- Case study: preparing a safety assessment report

Predictive Toxicology

- Introduction to predictive models
- In silico tools for toxicity prediction
- Advantages and limitations of predictive toxicology
- Regulatory acceptance of predictive models
- Case studies in predictive toxicology

In Vitro Safety Testing

- Overview of in vitro models
- Advantages of in vitro testing
- Regulatory considerations
- Types of in vitro assays used in safety testing
- Case studies of in vitro testing in drug development

Advanced Preclinical Data Analysis

- Data analysis techniques
- Interpretation of toxicological data
- Statistical significance in safety studies
- Reporting and communicating results
- Case study: data analysis in toxicology

Integrating Safety Data into Clinical Trials

- From preclinical to clinical phase
- How safety data impacts clinical design
- Regulatory considerations for transition
- Risk management strategies
- Case study: integrating safety data

Safety in Biopharmaceutical Development

- Unique challenges in biopharma safety
- Biotechnology vs. traditional drug safety testing
- Immunogenicity and its impact on safety
- Risk assessment in biologics
- Case study: safety issues in biopharma

Emerging Technologies in Safety Assessment

- Nanotechnology and its safety concerns
- Gene editing and safety assessments

- Artificial intelligence in toxicology
- Advances in predictive toxicology
- Case studies: Future trends in non-clinical safety

Ethical and Legal Considerations in Non-Clinical Safety

- Ethical issues in animal testing
- Regulatory frameworks and animal welfare
- Legal aspects of safety assessments
- Alternative testing methods
- Case study: ethical challenges in non-clinical safety testing

Case Studies in Non-Clinical Safety

- Industry case studies on safety failures
- Lessons learned from preclinical safety studies
- Case studies: Best practices for conducting safety assessments
- Innovative solutions for common issues
- Key takeaways from real-world examples

Training Methodology

- Interactive Online Learning.
- Case Study Discussion.
- Expert-Led Sessions.
- Assessments and Quizzes
- Collaborative Group Work.
- Hands-On Workshops.

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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