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# Beginners Guide to Toxicology

Learn the principles of practical toxicology

6 MODULES | 6-WEEK ONLINE COURSE | 25 March - 3 May 2024 | 21 October - 29 November 2024

Online Program

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# Course Information

## Key Learning Objectives

- Learn the principles of practical toxicology
- Understand the role of toxicology in the different phases of drug development
- Learn the principles of regulatory toxicology
- Main toxicology studies and related disciplines
- Understand the definition and role of “toxicokinetics”
- Toxicology terminology
- Understand description concept of ‘safety margins’
- Gain insights through practical case studies

## Why Should You Attend

The development of a pharmaceutical product is a stepwise process involving an evaluation of both animal and human efficacy and safety information. The goals of the safety evaluation generally include a characterization of toxic effects with respect to target organs, dose dependence, relationship to exposure, and, when appropriate, potential reversibility.

This information is used to estimate an initial safe starting dose and dose range for the human trials and to identify parameters for clinical monitoring for potential adverse effects. Serious adverse events determined in toxicology studies can influence the continuation of drug development.

Those involved in drug development should be aware of the toxicology requirements for marketing approval. This will allow non-toxicologists to learn the jargon and be able to effectively communicate with their colleagues.

This toxicology training program will discuss the basics of toxicology to allow non-specialists to understand the content of a toxicology report. This will be also accomplished with dedicated case studies during the clinical toxicology course to optimise learning.

## About the Course

The non-clinical safety assessment for marketing approval of a pharmaceutical product usually includes pharmacology studies, general toxicity studies, toxicokinetic and non-clinical pharmacokinetic studies, reproduction toxicity studies, and genotoxicity studies.

For drugs that have special cause for concern or are intended for a long duration of use, an assessment of carcinogenic potential is also required. Other non-clinical studies to assess phototoxicity, immunotoxicity, juvenile animal toxicity, and abuse liability are conducted on a case-by-case basis.

For biotechnology-derived products, appropriate non-clinical safety studies should also be conducted on a case-by-case basis. Non-clinical safety studies and human clinical trials should be planned and designed to represent an approach that is scientifically and ethically appropriate.

In toxicology, it should be possible to distinguish expected pharmacology (related to the mechanism of action of the drug) from unexpected or abnormal pharmacology. It should also be possible to rank molecules based on their intrinsic toxic potential and to identify potential adverse effects.

These effects should be correlated in toxicology with exposure to assess the presence of a dose-response.

Overall toxicology studies should allow the extrapolation from non-clinical data of the human situation. This will allow the inclusion of suitable assessments during clinical development to ensure that the safety of the enrolled subjects (either healthy volunteers or patients) is maintained.

In addition, toxicology studies should allow for the identification of patients at higher risk of an adverse event that should be excluded for the initial phases of drug development if this is deemed necessary. This clinical toxicology course will cover these aspects that are relevant for non-toxicologists involved in drug development.

## Who Will Benefit

Our toxicology training courses are beneficial to everyone involved in drug development.

- Clinical research associates
- Medicinal chemists
- Pharmacologists
- Toxicologists
- Project managers
- Business development managers
- Medical writers

# Meet Your Course Director

**Dr. Stefano Persiani**

Director of Translational Sciences and Pharmacokinetics, Rottapharm Biotech, Italy

Dr. Persiani is currently Director of Translational Sciences and Pharmacokinetics at Rottapharm Biotech, Italy. After years working in academia, Dr. Persiani moved to the pharmaceutical industry and CRO sector holding different positions in R&D at Farmitalia Carlo Erba, Pharmacia, Upjon, and Zambon Group.

His experience within pharmaceutical companies and CROs ranges from drug discovery and lead optimization to early preclinical and full clinical development in different therapeutic areas including oncology, respiratory, CNS, anti-infective, cardiovascular, gastrointestinal, and rheumatology.

# Course Outline

**MODULE 1:**

- Session 1. Objectives and Introduction
- Session 2. Non-clinical Testing for Medicinal Substances
- Session 3. Role of Toxicology Studies

**MODULE 2:**

- Session 4. Toxicology Studies

**MODULE 3:**

- Session 5. Regulations in Toxicology
- Session 6. Role of Toxicokinetics in Toxicology

**MODULE 4:**

- Session 7. Toxicological Considerations and Interpretations for Different Drug Classes

**MODULE 5:**

- Session 8. In-house vs Contracted out Toxicology Studies
- Session 9. Toxicological Challenges with Biotechnology Products (Biologicals)
- Session 10. Toxicological Studies with Established Drugs
- Session 11. Toxicology Limitations

**MODULE 6:**

- Session 12. Challenges for Toxicologists and Emerging Technologies

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## Easy Ways to Register

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## Fundamentals of Pharmacokinetics for the Non-Specialist

| Course Code | Location/ Format | Course Dates | Standard Price | |
|---|---|---|---|---|
| P24G50ON | Modular | 25 March - 3 May 2024 | $2,095 + $209.50 GST | **$2,304.50** |
| P24G50ON02 | Modular | 21 October - 29 November 2024 | $2,095 + $209.50 GST | **$2,304.50** |

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