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Academy

Beginners Guide to Toxicology

A Comprehensive Beginners Guide to Toxicology in Drug Development – Understanding Assessments, Risk Identification, and Clinical Implications.

Scheduled Digital/Online Course | 6 Self-Paced Modules over 5 Weeks

Click here to visit website

Course Information

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Course Overview

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.

Key Benefits

- 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.

Who Should Participate

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

Course Requirements and Certificates

Delegates must meet two criteria to be eligible for an Informa Connect Academy Certificate of Completion:

- **Satisfactory attendance** - Delegates must attend all sessions of the course. Delegates who miss more than 2 hours of the course sessions will not be eligible to sit the course assessment
- **Successful completion of the course assessment** - Assessments will be ongoing and based on in-class participation and activities

Delegates who do not meet these criteria will receive a Certificate of Attendance. If delegates have not attended all sessions, the certificate will clearly state the number of hours attended. In-person delegates will receive a printed certificate and virtual delegates will receive a digital certificate.

Course Outline

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Module One:

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

Module Two:

- Session 4. Toxicology Studies

Module Three:

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

Module Four:

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

Module Five:

- 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 Six:

- Session 12. Challenges for Toxicologists and Emerging Technologies

Course Director

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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.

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BOOK NOW

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Informa Connect Academy

Informa Connect Academy is a premier provider of global education and training solutions that caters to a diverse range of professionals, industries, and educational partners. We are dedicated to promoting lifelong learning and are committed to offering learners expert guidance, training, and resources to help them stay competitive in a rapidly changing world.

Our comprehensive range of courses and programmes are tailored to meet the needs of all professionals, from aspiring specialists to seasoned experts. We partner with elite academic organisations and industry leaders with unmatched expertise in their respective fields to deliver an exceptional learning experience.

ABOUT TIMINGS, PRICING AND DOCUMENTATION

Course fees include documentation, luncheon and refreshments for in-person learners. Delegates who attend all sessions and successfully complete the assessment, will receive a Informa Certificate and any applicable partner certificates. A hard copy will be provided to in-person learners and a soft-copy will be provided to virtual learners.

AVOID VISA DELAYS – BOOK NOW

Delegates requiring visas should contact the hotel they wish to stay at directly, as soon as possible.

To avoid delays, please ensure you apply for your visa several weeks before your intended travel date. Visa processing times can vary.

REGISTRATION, PAYMENTS AND CANCELLATION

All registrations are subject to our terms and conditions which are available at https://informaconnect.com/delegate-terms-and-conditions**.** Please read them as they include important information. By submitting your registration, you agree to be bound by the terms and conditions in full. All registrations are subject to acceptance by Informa Connect which will be confirmed to you in writing.

A confirmation letter and invoice will be sent upon receipt of your registration. Please note that full payment must be received prior to the course. Only those delegates whose fees have been paid in full will be admitted to the course.

For full cancellation details, please visit https://informaconnect.com/delegate-terms-and-conditions. All cancellations must be sent by email to training@informa.com.au marked for the attention of Customer Services Cancellation. Due to unforeseen circumstances, Informa Connect reserves the right to cancel the course, change the programme, alter the venue, speaker or topics. For full details, please visit www.informaconnect.com/academy.

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