ONLINE COURSE

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BEGINNERS GUIDE TO TOXICOLOGY

Learn the principles of practical Toxicology

6 Modules | 6-week online course 2 August – 10 September 2021

Our Expert Course Instructor

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.

Key Learning Objectives

- Learn the principles of practical toxicology
- Understand the role of toxicology in the different phases of drug development
- Learn 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

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ABOUT THE COURSE

The nonclinical safety assessment for marketing approval of a pharmaceutical product usually includes pharmacology studies, general toxicity studies, toxicokinetic and nonclinical pharmacokinetic studies, reproduction toxicity studies, 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 nonclinical studies to assess phototoxicity, immunotoxicity, juvenile animal toxicity and abuse liability are conducted on a case-by-case basis.

For biotechnology-derived products, appropriate nonclinical safety studies should also be conducted on case-by-case basis. Nonclinical 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. Toxicity should also allow to rank molecules based on their intrinsic toxic potential and to identify potential adverse effects.

These effects should be correlated in toxicology with the exposure, to assess the presence of a dose-response. Overall toxicology studies should allow to extrapolate from non-clinical data the human situation. This will allow the inclusion of suitable assessments during clinical development to ensure that safety of the enrolled subjects (either healthy volunteers or patients) is maintained.

In addition, toxicology studies should allow 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. The course will cover these aspects that are relevant for non-toxicologists involved in drug development.

WHO WILL BENEFIT

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

EXPERT COURSE INSTRUCTOR

Dr. Stefano Persiani
Director of Translational Sciences and Pharmacokinetics, **Rottapharm Biotech**, Italy

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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.

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 nonclinical 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 what are the toxicology requirements for marketing approval. This will allow non-toxicologists to learn the jargon and be able to effectively communicate with colleagues. In addition, the course will describe 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 course to optimize learning.

Would You Like To Run This Course On-Site?

Informa Corporate Learning: On-site & Customised Training

If you have **8+** interested people, an onsite course can be an ideal solution. Speak with **Anton Long** on **+61 481 995 653** or **Holly Baldwin** on **+61 450 866 597** to discuss your customised learning solution, or email **training@informa.com.au**

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Course Outline

6 Recorded Modules each lasting 45 minutes. Plus two recorded case studies.

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

BENEFITS OF LEARNING ONLINE

Informa Corporate Learning's online courses are new digital, interactive and engaging educational experience designed to maximise learning for professionals with busy schedules and/or small training budgets.

Our online courses are perfect opportunity for busy professionals as they require just 2 hours per week of your time and include an interactive forum for you to ask direct questions about challenges you are facing to expert course leaders.

Modules are released on a weekly basis, so you can pace yourself alongside your peers and you will have access to a comprehensive set of assets to support your learning such as video content, quizzes and case studies.

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Easy Ways to Register

1. **Web**
   www.informa.com.au/toxicology
2. **Telephone**
   +61 (0) 2 9080 4032
3. **Email**
   training@informa.com.au

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Course Code	Location	Course Dates	Standard Price		4+ Dels Discount
P21GO50ON	Online	2 August – 10 September 2021	$1,459 + 145.90 GST	**$1,604.90**	**Great Savings:** When you book **4 or more** participants! **Call us** today on **+61 (0) 2 9080 4032** or email **training@informa.com.au** to take advantage of the discount offer.

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If you have 8+ interested people, an on-site course can be the ideal solution – giving you the opportunity to customise our course content to your specific training needs, as well as attracting significant savings compared to public course costs.

Why Choose On-site With Informa Corporate Learning?

1. **Custom design** – Together, we will identify the best blended learning solution for your culture, your people and your training objectives.
2. **Quality Assured** – We design market-leading training programs, concepts and methodologies, with a 400+ course portfolio. Our rigorously selected 900+ instructor faculty are recognised experts in their field. Quality of their content and delivery methods is assured through continuous monitoring and evolution.
3. **On-site training** is a cost effective way to train your people and achieve your defined outcomes.

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