INTRODUCTION TO TOXICOLOGY FOR THE NON-SPECIALIST

25-26 November 2014
Radisson Blu Edwardian Grafton, London, UK

Learn all you need to know to communicate effectively with toxicologists

- Understand the what, how and why of toxicology
- Decipher jargon surrounding toxicology studies
- Review a range of late phase failures due to unexpected toxicity, examine why this occurred and how the decision making process could be improved
- Gain insight into the crucial issue of acceptable safety margins for drugs in different therapeutic areas
- Understand how packages for first into human studies are developed
- Examine the essential differences between clinical and preclinical toxicology
- Learn what is new in toxicology evaluation

"Very informative, delivering the basics of toxicology. Good reference material"

Research & Development Project Leader, Boehringer Ingelheim

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Performance & Knowledge Objectives of this Course:
• Gain a better understanding of toxicology at a level which is easy to grasp
• Understand the importance of toxicology studies and where they fit in the drug development cycle
• Study a range of examples of drugs which have failed in late stages of development due to toxicity
• Gain insight into toxicity issues across a range of drug administration routes
• Explore the huge range of disciplines in toxicology along with how they fit into the jigsaw of drug safety studies
• Examine case studies of toxicology of NCEs and biologics
• Learn how to apply the knowledge gained to be more effective in your role

Course Objectives:
Have you ever wondered why the toxicologist has had to terminate a promising candidate molecule early in development?
This course will explore the various aspects of toxicology, from the regulations to the multiple disciplines, so you fully understand the reasoning behind big decisions.
As many late stage failures and drug recalls result from unexpected toxicity in humans, a wider understanding of this field could help identify these problems earlier in development. Toxicology is a huge discipline, daunting if you need to speak intelligently to your toxicologists. This hands-on training course will give you everything you need to know to get a grip of this fascinating subject and increase your confidence when interacting with specialists.

The boundaries between disciplines in preclinical and clinical research are blurring as new technologies create ever more data to support drug submissions. The regulatory authorities are keen to support multi-disciplinary cooperation. For this reason you have to interact with a wider variety of disciplines, each of which has an astonishing breadth of knowledge amongst its specialists

Who should attend?
This course is aimed at anyone who comes into contact with toxicology data but does not require specialist knowledge in this field. No previous knowledge of toxicology is assumed. It will be of particular benefit to professionals working in:
• Development
• Preclinical
• Phase I
• Licensing
• Clinical Operations
• Project Management
• Regulatory Affairs
• Data Management
• Drug Safety
• Clinical Pharmacology
• Registration

About your PTI training course - Why should you choose this course?
• All PTI programmes are developed following extensive research with the industry, to ensure that the objectives of each course match your objectives.
• Focusing on your business issues during our research ensures that each and every course can help you deliver immediate results when you are back in your office.
• Application and implementation of industry knowledge and experience is the driver for our course design. Not theoretical, academic lectures.
• Featuring a blend of interactive learning tools, including case studies, group discussions, scenarios, simulations, practical exercises and knowledge assessments; PTI courses focus on practical techniques.

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Course Agenda

DAY ONE

09.15am Introduction
The course will commence with an introduction from the trainers followed by input from participants on their previous knowledge and objectives for attending the course.

The role of toxicology in drug development
- What is toxicology and how is it evaluated?
- Why do we perform toxicology studies?
- The importance of toxicology throughout phases of drug development and the increasing importance of toxicology in go/no go decisions
- Toxicology and the regulatory authorities
- Toxicology as a strategy tool - establishing what is needed and interpreting results
- Interdisciplinary interaction in the pharmaceutical industry - let's all speak the same language

How drugs cause toxicity - what do we measure and how do we measure it?
- How do we measure toxicity?
- Risk vs hazard assessment
- Establishing what we are studying and why
- Explaining basic terminology
- Introducing the range of toxicology study types from single dose to lifetime exposure
- What toxicological endpoints are measured?
- Assessing appropriate dose and safety margins for first into man studies
- Selecting the appropriate species for toxicological evaluation

The place of toxicology studies in the regulatory world
- Regulatory guidelines
- Impact of ICH on toxicology studies
- Toxicology data required for clinical trials and submission dossiers
- How toxicology testing is constantly evolving
- The toxicologist at regulatory meetings

The toxicologist in the project team
- Medicinal chemistry/pharmacy interaction (eg need for sizeable amount of drug product, useable formulation, 'accepted' excipients, GMP material)
- Clinical medical interaction (eg need to establish safety for human use, identify toxicological risk/safety margins, ensure adequate safety through development, advise on new risks)
- Regulatory affairs interaction (eg supply of scientific documentation to support regulatory process, data for regulatory meetings, clinical trial work and product licence application, postmarket support)
- Project leader (and marketing) interaction (eg support to make go/no go decisions, identify risk and delays, help a 'speedy but safe' process)

Setting up and running toxicology studies
- Setting up a toxicology study from draft protocol to final report
- Details on study designs
- Legislative considerations - concerns for animal welfare

Toxicological disciplines - what are they & how do they differ?
- Safety pharmacology
- General toxicology
- Genetic toxicology
- Reproductive toxicology
- Carcinogenicity
- Local tolerance

GROUP DISCUSSION AND CASE STUDIES
As a toxicologist in your company, you need to design an appropriate package of safety pharmacology and toxicology studies to support initial clinical trial work. Proposed studies and the rationale for their inclusion will be discussed.

The role of toxicokinetics in toxicology
- Basics of toxicokinetic testing
- Toxicokinetic measurement in toxicology studies
- Establishing safety margins for clinical investigations
- Extrapolation to man: What is the relationship between preclinical and clinical toxicology?
- Microsampling update

CASE STUDY AND GROUP DISCUSSION
During a project meeting you learn that a change in the manufacturing process is planned for economical reasons. Analytical results indicate a change in impurity profile for your drug which is in late clinical development. New toxicological needs will be discussed.

DAY TWO

Interpreting results and their implications
- Assessing in-life data, clinical pathology, necropsy and histopathology data
- Presenting results
- Common pitfalls
- What do toxicology study findings mean?
- What impact do unexpected findings have on product development?
- Understanding the limitations of toxicology studies
- The need to utilise data from the various toxicology disciplines
- Working with common toxicity findings such as renal or liver toxicity or ‘expected’ tumour findings

Toxicological challenges with biotechnology products (biologics)
- Why are these drugs different?
- What are the challenges for toxicologists?
- Designing toxicology studies on a case-by-case basis
- Assessing what is toxicity vs pharmacology or immunogenicity
- Increased need for regulatory agency interaction

CONTROL SAMPLE CONTAMINATION
The control toxicokinetic blood samples from a key regulatory study are found to be contaminated with test compound. The implications and how they can be addressed will be discussed.

Effects of administration route on toxicology
- Considerations on study design for drugs to be dosed orally vs by parenteral (including continuous infusion), inhalation and nasal routes
- What different “toxicities” might occur?

Other challenges for toxicologists
- QT prolongation – where do we stand?
- Drug contamination in control samples
- Juvenile animal toxicity testing to support paediatric clinical trials
- Immunotoxicity within toxicological evaluation
- Toxicological issues with novel excipients

CASE STUDY
Your company has a lot of experience in developing small synthetically produced drugs but is moving into the development of biological molecules. As a toxicologist, you need to design a package of studies to support such development. Discussion of specific issues will occur, including: correct species selection, antibody formation to a ‘foreign’ protein, pharmacological vs toxicological effects, the lack of need for genotoxicity testing, how to approach reproduction toxicity testing and clinical starting dose.

Toxicological studies for established drugs
- Participants will gain an overview of toxicological considerations/requirements for:
  - Line extensions (eg new formulations)
  - Generics

CASE STUDY
Your drug is licensed for one dose route (eg oral) and a new marketing opportunity is identified for a different route (eg inhalation). Toxicological support to allow this clinical change will be identified and discussed.

Newer technologies in toxicology
Now that you have a good understanding of classical methods and roles of toxicology in drug development, what does the future hold?

The most exciting new developments include:
- The impact of ‘omics’ technologies on toxicological evaluation
- In silico predictive toxicology
- In vitro toxicology
- Microdosing in safety assessment
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