Training Course

ADME, PK/TK, and Drug Metabolism in Drug Discovery and Development

January 23rd and 24th 2007
Sheraton Brussels Hotel and Towers
Brussel, Belgium

Who Should Attend

This course is specifically designed for personnel in the pharmaceutical and biotechnology industries and contract research organizations (CROs) who need to understand the requirements for ADME (absorption, distribution, metabolism, elimination), pharmacokinetics (PK) and toxicokinetics (TK), and drug metabolism (DM) experiments during the drug discovery and development processes.

Participants should have some knowledge of these processes and desire to learn more about how ADME, PK/TK, and DM studies are designed, conducted, and interpreted in order the characterize the fate of a drug candidate. Nonclinical and clinical scientists, managers, and project team leaders at pharmaceutical companies and related industries will gain a detailed understanding of the types of ADME, PK/TK, and DM research studies conducted to support submissions to regulatory authorities.

Learning Objectives

Upon completing this course, participants will have knowledge of the research studies conducted to characterize the fate of a drug candidate, either a small organic molecule (NCE) or macromolecule, after administration to animal models and humans. Participants will learn about and understand the requirements for ADME, PK/TK, and DM studies conducted to select the optimal drug discovery lead (developability assessment), to support first-in-human clinical trials, and to compare and extrapolate metabolism profiles from animal models to humans.

Course Description

The content of this course will assist pharmaceutical, biotechnology, and CRO researchers and managers in understanding the requirements for a well-designed and successful ADME, PK/TK, and DM program that is conducted within a drug development logic plan and in compliance ICH guidelines. The various types of ADME, PK/TK, and DM studies, which include in vitro metabolism and delivery, animal and human pharmacokinetics, protein binding, mass balance, tissue distribution, metabolite isolation and identification, and toxicokinetic support, will be discussed. Study designs and potential results, with possible interpretations, from each of the study types will be presented. The generation study reports and summaries, both of which are to be included in submissions to regulatory authorities, for completed research experiments will be delineated.

Course Instructor

The course willl be taught by Dr. Duane Lakings. Dr. Lakings has over 25 years of experience in drug discovery and developability assessment, preclinical and non-clinical development, and clinical development and has designed and conducted animal and human research studies on both small organic molecules and macromolecules. His primary areas of expertise include pharmacokinetics and toxicokinetics, drug metabolism and ADME, drug delivery, and bioanalytical chemistry and he has excellent knowledge of the pharmacology, toxicology, and clinical requirements for successful drug development.

During his career, he has been involved in characterizing drug candidates for a number of therapeutic diseases and disorders, including CNS, cardiovascular, metabolic diseases, oncology, infectious diseases (bacterial and viral), and dermatology. He has used his knowledge to assist clients with defining drug development logic plans, selecting and managing CROs, and preparing study reports for completed nonclinical and clinical research studies.

Dr. Lakings has authored over 40 publications, 10 commissioned reports, 5 book chapters, and over 200 company-specific technical reports. He has made numerous scientific presentations at various society meetings and as an invited speaker at pharmaceutical and biotechnology companies. His expertise in the pharmacology and toxicology aspects of drug development and his experience in the research studies needed for the characterization of drug candidates and in scientific document preparation have led to many successful submissions to regulatory authorities.

Dr. Lakings is a member of many professional societies and associations, including the American Association for the Advancement of Science, American Association of Pharmaceutical Scientists, American Chemical Society, International Society for the Study of Xenobiotics, American Medical Writers Association, the Society of Sigma Xi, and Alpha Chi Sigma.

COURSE AGENDA

DAY ONE

Session 1: Introduction and Overview (8:30 – 10:00 AM)

- Purpose and Goals
- Drug Discovery and Development Logic Plan
- Types of Drug Metabolism and ADME Studies
- GLP Regulations Overview

Session 2: Developability Assessment Experiments (10:30 AM to noon)

- In Vitro Delivery and Example Profiles
- Preliminary Protein Binding
- In Vitro Metabolism
- Bioanalytical Chemistry Method Definition
- Preliminary Pharmacokinetics and Example Profiles
- Bioavailability and Example Profiles

Session 3: Preclinical Drug Development Experiments – Part 1 (1:00 to 2:30 PM)

- Bioanalytical Chemistry Method Validation
- Pharmacokinetic Assessments in Toxicology and Pharmacology Animal Species
- Absolute Bioavailability and Dose Proportionality Examples

Session 4: Preclinical Drug Development Experiments – Part 2 (3:00 to 4:30 PM)

- Toxicokinetics
  - Multiple Dose Evaluation Examples
  - Gender Effect Examples
- Drug Candidate Radioisotopic Labeling
  - Choice of Label and Labeling Site
  - Radiochemical and Metabolic Stability Evaluations
- Mass Balance in Toxicology Species
  - Metabolic Profiling Assay
  - Study Design and Sampling Recommendations
  - Extent of Metabolism
  - Route(s) and Rate(s) of Elimination
- Definitive Protein Binding in Various Species

DAY TWO

Session 5: Clinical Drug Development Experiments (8:30 to 10:00 AM)

- Types of Human ADME and Drug Metabolism Experiments
- Human Pharmacokinetic Evaluation Examples
- Drug-drug and Drug-Food Interactions
- Stereochemistry Issues
- Bioavailability and Bioequivalence Evaluations
- Renal and Hepatic Impairment Studies
- Age Effects

Session 6: Nonclinical Drug Development Experiments (10:30 AM to noon)

- Toxicokinetic Support
  - Feto-placenta Transfer and Lacteal Secretion Toxicokinetic Studies
- Tissue Distribution (Single– and Repeat–Dose) and Whole Body Audioradiography
- Studies Design and Sampling Requirements
- Metabolite Isolation and Identification
  - Development and Validation of Bioanalytical Method(s) for Metabolites
  - Pharmacokinetic Evaluation of Metabolites
- Definition of Metabolism Pathway
- Induction and Inhibition of Drug Metabolizing Enzymes
- Animal Bridging Studies

Session 7: Clinical Drug Metabolism and ADME (1:00 to 2:30 PM)

- Study Protocols
- Technical/Study Reports
- Test Assay Methods
- Standard Operating Procedures
- Summaries for Submission to Regulatory Authorities

Session 8: Documentation (3:00 to 4:30 PM)

- Summary and Conclusions
- Workshop to Design and Discuss ADME and Drug Metabolism Studies Needed to Support the Discovery and Development of Various Drug Candidate Types – The Logical Approach to Discovery Lead Selection

For more information contact:

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☐ **Discount 2 or more people**	**£ 1440**
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