

Informa Connect

Academy

Fundamentals of Pharmacokinetics for the Non-Specialist

Understand how pharmacokinetics (PK) data is used in drug development to improve regulatory submission efficiency

6 MODULES | 6-WEEK ONLINE COURSE | 4 March - 12 April 2024 | 7 October - 15 November 2024



Online Program

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Course Information

Meet Your Course Director

Key Learning Objectives

- Familiarise yourself with the key principles of pharmacokinetics, including absorption, distribution, metabolism and excretion
- Understand how to present pharmacokinetic results to the regulators
- Consolidate your knowledge with case studies and understand the relevance of pharmacokinetics in practice
- Address the fundamental areas of PK, including definitions, data analysis and regulatory expectations

Who Will Benefit

This clinical pharmacokinetics course is aimed at anyone who comes into contact with PK/PD data but does not require specialist knowledge in the field. No previous knowledge of PK/PD is assumed.

Relevant Departments include:

- Research & development
- Preclinical development
- Licensing and business development
- Clinical operations
- Regulatory affairs
- Clinical pharmacology



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 Information

Course Outline

About the Course

Pharmacokinetics is an important discipline imperative to the development of new medicines. With no prior knowledge assumed, this six-module pharmacokinetics online course will familiarise you with the core aspects of this field. You will learn essential definitions, how to analyse pharmacokinetic data, the relationship between pharmacokinetics and pharmacodynamics, drug-drug interactions and regulatory requirements. On top of this, you will be able to consolidate your knowledge with two case studies, both detailing practical uses of pharmacokinetics.

MODULE 1

FUNDAMENTALS OF PHARMACOKINETICS

Learning Outcomes

- Role of PK
- Absorption
- Distribution
- Metabolism
- Excretion
- Disposition

MODULE 2

PHARMACOKINETIC ANALYSIS

Learning Outcomes

- First and zero-order processes
- Non-compartmental analysis
- Compartmental analysis
- Elimination half-life
- Clearance
- Volume of distribution

MODULE 3

DRUG-DRUG ANALYSIS

Learning Outcomes

- Definitions of drug interactions
- Drug metabolism
- Enzyme inhibition and induction
- Reaction phenotyping
- Study design
- Transporter interactions

MODULE 4

REGULATORY GUIDELINES

Learning Outcomes

- PK results presentation
- Individual and mean PK profiles
- Variability in PK
- Crossover study design
- Statistical analysis
- Sample size calculation
- First in-man guideline

MODULE 5

PK/PD STUDIES

Learning Outcomes

- Single and multiple-dose PK studies
- Linear PK
- Absolute and relative bioavailability and bioequivalence
- Food effect study
- Biomarkers
- Direct vs indirect PK/PD
- Hysteresis

MODULE 6

PHARMACOKINETICS OF BIOLOGICS & POPULATION PHARMACOKINETICS

Learning Outcomes

- Definitions of biological drugs
- Biological drugs ADME
- PK of biological drugs guideline
- Fundamental of population PK
- Role of population PK
- Application of population PK

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Easy Ways to Register



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Informa Connect

Academy

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- 3. On-site training** is a cost effective way to train your people and achieve your defined outcomes.

Speak with **Sushil Kunwar** on **+61 (2) 9080 4370** to discuss your customised learning solution, or email inhouse@informa.com.au