Pharmacokinetics in Drug Development - an Integrated Approach - for the non-specialist

PharmaTraining

18 & 19 June 2018, London UK

PK understanding to aid your drug development

Overview

In drug development clinical pharmacology is tasked to ensure that patients receive the right dose at the right time. This ensures that the new medicine is safe and effective throughout the patient population. To achieve this goal, it is necessary to recognise the factors that can alter drug response. Knowledge of pharmacokinetics (PK) and pharmacokinetic/pharmacodynamic (PK/PD) relationships is at the heart of this endeavour. For many drugs, clinical pharmacology information accounts for almost 50% of the final drug label, further emphasising the importance of PK understanding in drug development.

Course Objectives:

To provide participants with an overview of the principles of PK and PK/PD modelling and how, together with regulatory guidances, they can be used to effectively deliver drug development programmes

What will participants gain?

- Increased confidence to discuss PK issues within their drug projects
- Understanding of the common PK terms and their importance
- Understanding of how PK data influences the clinical development Programme
- An understanding of the factors that contribute to variability in PK
- The role of PK/PD modelling in drug development
- An appreciation of how regulatory guidances influence PK

Who Should Attend?

The course is intended for all professionals in the drug development arena especially those that work in or with clinical project teams (eg Regulatory Affairs specialists; Medical personnel; Project Managers/ Leaders; Clinical Research Associates; Medical Writers) who want to further their knowledge of the usefulness of PK in their projects.

Comment from previous attendee:

"Very good, certainly useful, really made me see things from a different perspective rather than just as a formulator!"

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Course objectives:

To provide participants with an overview of the principles of Pharmacokinetics and Pharmacokinetic/Pharmacodynamic modelling and how together with regulatory guidances they can be used to effectively deliver drug development programmes.

Course will commence with registration from 8.30am, course proper at 9.00am and will finish at 5.00pm each day.

Course Programme

Day 1: Pharmacokinetic Principles

What is PK and why is it important?

- Absorption, distribution, metabolism and elimination
- Therapeutic windows
- PK terminology
- Clearance, Volume of distribution

PK techniques

- Non compartmental Analysis
- Compartmental modelling
- PK/PD modelling
- Physiologically based PK modelling
- Regulatory environment
- Data interpretation
- Reporting

Day 2: PK in Drug Development

The application of PK in clinical development will be addressed by looking at questions that commonly arise within drug projects. Examples include: 'What are the implications of pre-clinical PK findings on the design of early phase development studies?'; 'How is the clinical relevance of a drug interaction assessed?' and 'What are the sources of variability in pharmacokinetic response?'.

Early phase development

- Dose choice in first in human studies
- Drug interactions; CYPs and transporters, strategies and regulatory guidance; types of interaction competitive vs mechanism based; comedication strategy for patient studies
- Radiolabel studies to assess routes of elimination
- Assessing bioequivalence (oral and inhaled routes)

Variability in PK

- Genetic polymorphisms
- Influence of age
- Food effects

Several "learning in action" workshops during both days will provide participants with the opportunity to apply knowledge gained during the lectures.

Participants will need to bring along a scientific calculator

Comment from previous attendees:

"Good content, presentation and pace!"

"very useful, everything makes a lot more sense now"

An open forum session will be held where delegates can bring along their own issues for discussion.

Venue:

London: DoubleTree Hilton, (formerly Jury's Inn) 60 Pentonville Road, Islington London N1 9LA
Website: www.doubletree3.hilton.com

Accommodation and travel directions are available on our website

www.pharma-training-courses.com

Course Speaker: Dr Graham Blakey

Graham graduated with a BSc (Hons) degree in Pharmacy before undertaking various roles in hospital pharmacy. He gained an MSc in Clinical Pharmacology from the University of Glasgow. This experience developed Graham's interest in pharmacokinetics and lead to a PhD with Prof Malcolm Rowland at the University of Manchester. His thesis was entitled 'Tissue kinetics of a series of barbiturates'.

Graham spent 12 years with AstraZeneca Charnwood where he held several roles including Principal Scientist and Head of Clinical Pharmacokinetics. During this time he gained extensive experience in providing clinical pharmacology strategy including pharmacokinetic/pharmacodynamic input and analysis to all phases of clinical drug development. Graham has worked in many global project teams, as a clinical pharmacokineticist and project leader, in several therapeutic areas including: inflammation, cardiovascular and CNS. Output from these teams has supported drug development in Europe, Japan and North America.

Graham has a particular interest in the determination of clinically relevant drug interactions. Throughout his career he has pioneered the use of probe drugs (including the cocktail approach) as clinical markers of the activity of the Cytochrome P450 drug metabolising isoenzymes. His work in inflammation centred on rheumatoid arthritis and osteoarthritis and saw several novel compounds progress from pre-clinical to patient studies. Graham now works in consultancy providing clinical pharmacology and pharmacokinetic expertise.

For 5 or more staff requiring training it may be beneficial to run a course in-house.

The benefits of running a course in-house:

- Save on travel or accommodation costs
- Customised content to meet your requirements
- Big print savings on course material - especially with larger groups
- Courses arranged for large groups up to 24 staff
- Tutorials available for small groups of 2 or 3 staff
- Meet course speakers in advance to discuss design and content

Contact **Judy Callanan at any time to discuss**
Ph: 0044 (0)20 8133 2605, Email: judy@pharma-training-courses.com

REGISTRATION DETAILS:

Pharmacokinetics in Drug development - an integrated approach for the non-specialist

18 & 19 June 2018, London
Early-bird rate: £1080.00 for registering and paying by 18 May 2018
(+ VAT if applicable, see VAT rules)
Full Fee: 2 day course £1200.00 (+ VAT if applicable, see VAT rules)

Academic rates are available, please contact Judy Callanan by email info@pharma-training-courses.com

VAT RULES:
UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.
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Online Registration is available on our website:
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Terms and Conditions

Delegate fees

Fees for this programme or suite of programmes are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you.

Cancellation Policy

Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time.

Liability

PharmaCourses Ltd reserves the right to change the programme, speakers, date or venue without notice or cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid.

PharmaCourses Ltd will not be responsible for any airfare, accommodation or other travel costs incurred.

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Course Programme 2018

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 March 2018, **Croydon Greater London**

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HPLC Analytical Method Development and Validation
10 & 11 May 2018 **Istanbul Turkey**

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Stability Testing in Pharmaceutical Development and Manufacture
24 & 25 May 2018 **London**

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Pharmaceutical Dissolution Testing – a 2 day course
21 & 22 May 2018 **London**

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Pharmacokinetics in Drug Development - an integrated approach
18 & 19 June 2018 **London**

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Pharmaceutical Packaging – an introductory course
25 June 2018 **London**

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Powder Technology for Pharmaceutical Development and Manufacturing
26, 27 & 28 September 2018 **London**

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Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 June, **Croydon Greater London**

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Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
24 & 25 September 2018 **London**

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Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs
24 & 25 September 2018 **London**

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Pharmaceutical Dissolution Testing – a Hands-on Course
23, 24, 25 & 26 October 2018 **London**

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Pharmaceutical Granulation and Compression
29, 30 & 31 October 2018 **London**

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GMP Auditor Training for Quality Systems
7, 8 & 9 November 2018 **London**

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Parenteral Products
12, 13 & 14 November 2018 **London**

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Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices
19, 20 & 21 November 2018 **London**

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Development of Stability-Indicating HPLC Methods
21 November 2018 **London**

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HPLC Analytical Method Development and Validation
22 & 23 November 2018 **London**