Pharmacokinetics in Drug Development - an Integrated Approach

PharmaTraining

9 & 10 June 2011
Window Conference Venue, London

PK understanding to aid your drug development programmes

The UK, like most developed countries, has an ageing population. In the 2001 population census, the average age was 39.0 years, an increase on 1971 when it was 34.1 years. In mid-2006 approximately one in five people in the UK were aged under 16 and one in six people were aged 65 or over. With advancing age comes increased medicine use, furthermore elderly patients are likely to be taking several concomitant medications. This greater drug usage makes them more at risk of suffering from adverse events as a result of drug drug interactions (DDIs). DDIs may be metabolic, transporter, physicochemical or dynamic in nature. In drug development, advances in *in vitro* science and modelling software have helped to screen out compounds that are most at risk of DDIs before they enter into man. The need to investigate DDIs in the clinic though has not disappeared. Several regulatory agencies have drug interaction guidances; in particular the FDA has recently released a draft guidance entitled 'Drug Interaction Studies-Study Design, Data Analysis, and Implications for Dosing and Labeling' that takes account of current thinking in the field. An understanding of the pharmacokinetic/pharmacodynamics of the compound, linked to the relevant regulatory guidances is required to deliver a safe and effective medicine that can be used by patients concomitantly with other remedies.

What will participants gain?

- 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 PKPD modelling in drug development
- An appreciation of how regulatory guidances influence PK
- Increased confidence to discuss PK issues within their drug 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.

Who will benefit:

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) who want to further their knowledge of the usefulness of PK in their projects.

Course will commence with registration at 8.30am, course proper at 9.30am and will finish at 5.00pm each day.

Course Programme

Day 1: Pharmacokinetic Principles

What is PK and why is it important

Adsorbtion, distribution, metabolism and elimination

- Transporters
- Drug failures
- Therapeutic windows

PK terminology

- Clearance, volume of distribution etc. What they are and what is their Importance

PK techniques

- Non compartmental Analysis
- Compartmental modelling
- Population pharmacokinetics
- Regulatory environment
- Data interpretation

Day 2: PK in Drug Development

Pre-clinical/clinical interface

- What PK data are available, how does this influence the Clinical PK strategy
- Biomarkers
- Implications for CTA-dose choice and dose escalation in first to man studies, adaptive dosing

Variability in PK

- Drug interactions; CYPs and transporter strategies and regulatory guidance;
- Types of interaction competitive vs mechanism based; implications for study design (restrictions healthy volunteers vs patients etc)
- Genetic polymorphisms
- Paediatrics

Biologics

- Pharmacokinetics/Pharmacodynamics
- Study Design
- Regulatory environment

Participants will need to bring along a scientific calculator

There will also be several "learning in action" workshops during both days where participants will have the opportunity to apply knowledge gained during the lectures. An open forum session will be held where delegates can bring along their own issues for discussion.

Venue

Window Conference Venue 13 Windsor Street, Islington London, N1 8QG convenient for central London, in a pleasant informal setting.

Course fee includes all course materials, refreshments, and lunch, accommodation is not included.

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.

COURSE PROGRAMME 2011

Planning for Commercial Launch: 29 & 30 March 2011
GMP Auditor Training: New Jersey USA - 11 & 12 April 2011
London - 9 & 10 May, 7 & 8 November 2011
How to Audit API Manufacturers: New Jersey USA - 13 April 2011
London - 11 May, 9 November 2011
Supply Chain Management in Pharma/Biotech: 5 & 6 May 2011
Technology Transfer: London - 9 & 10 May, 7 & 8 November 2011
Integrated Tablet Formulation Development: New Jersey USA - 7 & 8 April
London - 9 & 10 June, 24 & 25 November 2011
Tablet Process Development, Validation and the application of QbD:
New Jersey USA - 11 & 12 April, London - 13 & 14 June, 28 & 29 November
Pharmacokinetics in Drug Development - an Integrated Approach:
9 & 10 June 2011
An Introduction to LC/MS: 19 September 2011
Quantitative Analysis: 20 & 21 September 2011
Writing effective SOPs in a GMP Environment: 13 & 14 October 2011
OOS investigations in a GMP Environment: 18 & 19 October 2011
Stability Testing in Pharmaceutical Development: 16 & 17 May 2011,
12 & 13 December 2011
Introduction to Photostability: 14 December 2011
Pharmaceutical Packaging - an Introductory Course: 14 December 2011
HPLC Analytical Method Development and Validation: 22 & 23 November
Oral Solid Dosage Manufacturing Technology: 28 November 2011
Development and Manufacture of Effervescent Tablets: 30 November 2011

We deliver a range of expert programmes in pharmaceutical development, quality assurance and regulatory topics, plus a range of industry awareness courses. We employ speakers/trainers with a high degree of expertise, completely up to date with industry trends.

Please check our website for other courses added throughout the year.

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REGISTRATION FORM

Pharmacokinetics in Drug development—an integrated approach:

9 & 10 June 2011—London

2 day course £1180.00 + VAT £236.00 **Total £1416.00** ☐

Discounted rate for registering and paying before **6 April 2011**

2 day course £1062.00 + VAT £232.40 **Total £1294.40** ☐

Title (Mr/Mrs/Ms/Dr/Prof): First Name:

Surname:

Company:

Address:

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☐ Cheque (**Please make payable to "PharmaTraining Ltd")**

☐ Bank transfer ☐ Credit/Debit Card

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Online Registration is available on our website:

www.pharma-training-courses.com

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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

PharmaTraining 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.

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

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