An Integrated Approach to Pharmacokinetics in Drug Development

The Baltic Exchange,
38 St Mary Axe London UK
18 June 2008

Objective of Course

To provide participants with an overview of the principles of pharmacokinetics (PK) and of pharmacokinetic/pharmacodynamic (PKPD) modelling and how they fit together with the drug regulatory environment

Course overview

This new course provides participants with an integrated overview of pharmacokinetics in drug development. Pharmacokinetic terms will be explained and factors contributing to their variability will be discussed. How emerging data and the regulatory environment influence PK strategy will be covered through the use of examples from the literature and the speaker's own experience. Drug interaction, bioavailability (including inhaled compounds) and first in man studies will be considered. In addition the place of PKPD modelling and simulation (including population pharmacokinetics) in drug development will be presented. Delegate's knowledge will be further enhanced through participation in break out sessions where practical exercises and case histories will be examined.

Who will benefit from the course

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; Project managers/leaders; Clinical research associates) who want to further their knowledge of the usefulness of PK in their projects.

At the end of the course participants will have an

- Understanding of the common PK terms and their importance
- Understanding of how PK data influences the clinical development programme
- Insight into the factors that contribute to variability in PK
- Understanding of the role of PKPD modelling in drug development
- An appreciation of how regulatory guidances influence PK strategy

Programme

9.00	Introductions
9.10	What is PK and why is it important?
9.50	Pre-clinical/clinical interface
10.30	coffee
11.00	Factors influencing PK variability
12.10	Exercise
12.30	Lunch
1.30	Bioavailability and Bioequivalence
2.15	PKPD Modelling and simulation
3.00	Coffee
3.30	Case Study
4.30	Summary and questions
4.45	Close

Participants will need to bring along a scientific calculator

Course Speaker

Dr Graham Blakey, GBPK Consulting. 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 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 to the pharma industry.

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Numbers will be limited to give participants the opportunity for thorough discussion of the issues to be covered by the programme and one on one consultation with speakers.

For details of our terms and conditions please see our website www.pharmatrainingservices.com

REGISTRATION FORM

I wish to register for the following course	Please tick
An Integrated Approach to Pharmacokinetics in Drug Development **18 June 2008:** 1 day course £500 + Vat £ 87.50 Total £ 587.50	

Total payable £

Title (Mr/Mrs/Ms/Dr/Prof): _____First name _____

Surname: _____

Position: _____

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