Overview
This course will provide participants with a comprehensive introduction to pharmacokinetics (PK) and the principles of pharmacokinetic/pharmacodynamic (PK/PD) modelling. PK and PK/PD concepts will be considered alongside regulatory guidances to demonstrate how they can be used to deliver effective drug development programmes.

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 PK and 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.

Throughout the course participants will learn how to apply the knowledge gained to enable them to be more effective in their professional roles.

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
The principle processes involved in PK will be discussed and the jargon used in their description and estimation will be explained. The application of PK in drug development will be addressed through broadly answering the following questions.

What is PK and why is it important?
- Absorption, distribution, metabolism and elimination
- Therapeutic windows
- PK terminology including clearance and volume of distribution
- PK input into study design

How are PK parameters estimated and interpreted?
- Non compartmental Analysis
- Compartmental modelling
- PK/PD modelling
- Population PK
- Physiologically Based PK models
- Regulatory environment
- Data interpretation
- Reporting

How do biologics differ to small molecules?
- PK disposition
- Study Design
- Application of PK methodology
- Variability

How is pre-clinical PK information used?
- Candidate selection
- Therapeutic dose estimation

What are the aims of early phase development?
- Dose choice in first in human studies
- Drug interactions; CYPs and transporters
- Radiolabel studies to assess routes of elimination
- Assessing bioavailability and bioequivalence

How does variability in PK affect the dose?
- Pharmacogenetics
- Demographics
- Food effects
- Renal and hepatic impairment

Several “learning in action” workshops during both days will provide participants with the opportunity to apply the knowledge gained during the lectures. These include interactive quizzes (with prizes!), in addition to case histories covering the application of PK principles to drug development challenges

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: HILTON LONDON EUSTON
17-18 Upper Woburn Pl, Bloomsbury, London WC1H 0HT United Kingdom
Website: https://www3.hilton.com/

Hotel is within walking distance of Euston, St Pancras and Kings Cross Stations.
Accommodation and travel directions are available on our website
www.pharma-training-courses.com

Course Speaker: Dr Graham Blakey
Graham had been investigating the clinical pharmacology of new drugs and novel formulations for over 20 years. He currently runs a consultancy company based in Nottingham that provides clinical pharmacology, PK and regulatory solutions to the pharmaceutical industry.

At AstraZeneca he was a Principal Scientist in Experimental Medicine, where he was involved in the transition of several new chemical entities from discovery into humans. He is experienced in a number of PK methodologies and has used these across the drug development spectrum, from pre-clinical through to late phase patient studies. Graham is an advocate of creative and efficient clinical study design and has applied these principles to many global drug development projects in several therapeutic areas. His skills have involved him in various patent cases where he has acted as an expert witness.

Graham has developed professional PK training courses for both experts and non-experts working in the pharmaceutical and bioscience sectors. Additionally, he has provided PK teaching on a number of undergraduate and postgraduate degree courses.

Graham holds a degree in Pharmacy and is a member of the Royal Pharmaceutical Society. He has an MSc in Clinical Pharmacology from the University of Glasgow and a PhD from the University of Manchester.

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 November 2019 London
Early-bird rate: £1080.00 for registering and paying by 25 October 2019 (+ 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

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www.pharma-training-courses.com

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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.

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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 2019

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
10, 11 & 12 April 2019, Croydon Greater London
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Pharmaceutical Dissolution Testing – a Hands-on course
21, 22, 23 & 24 May 2019 London
***

Stability Testing in Pharmaceutical Development and Manufacture
6 & 7 June 2019 London
***

Pharmaceutical Packaging – an introductory course
17 & 18 June, 2 & 3 December 2019 London
***

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
26, 27 & 28 June, Croydon Greater London
***

Powder Technology for Pharmaceutical Development and Manufacturing
25, 26 & 27 September 2019 London
***

Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
16 & 17 September 2019 London
***

Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs
18 & 19 September 2019 London
***

Pharmaceutical Dissolution Testing – a Hands-on Course
8, 9, 10 & 11 October 2019 London
***

Parenteral Products
21, 22 & 23 October 2019 London
***

Pharmaceutical Granulation and Compression
11, 12 & 13 November 2019 London
***

GMP Auditor Training for Quality Systems
29, 30 & 31 October 2019 London
***

Development of Stability-Indicating HPLC Methods
14 October 2019 London
***

HPLC Analytical Method Development and Validation
15 & 16 October 2019 London
***

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices
25, 26 & 27 November 2019 London
***

Pharmacokinetics in Drug Development - an integrated approach
18 & 19 November 2019 London
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Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
4, 5 & 6 December 2019, Croydon Greater London
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