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!”

23 & 24 November 2020, London UK
PK understanding to aid your drug development

www.pharma-training-courses.com
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:

DoubleTree Hilton London Angel Kings Cross Hotel, 60 Pentonville Road, London, N1 9LA
Close to Angel, Kings Cross and St Pancras 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

23 & 24 November 2020 London
Early-bird rate: £1080.00 for registering and paying by 8 October 2020 (+ 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.
EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT PROVIDED THAT valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.
OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Data Protection
PharmaTraining Ltd gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. If you have any queries or want to update any of the data that we hold then please contact us.

Online Registration is available on our website: www.pharma-training-courses.com

PharmaCourses Ltd is Registered in England and Wales No. 08509096

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.

PharmaCourses Ltd, Suite 1327, Kemp House, 152 City Road, London EC1V 2NX
Tel: 0044 (0)2071937703 Email: info@pharma-training-courses.com

www.pharma-training-courses.com
Course Programme 2020

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
1, 2 & 3 April and 2, 3 & 4 December 2020, Croydon Greater London

Pharmaceutical Dissolution Testing – a Hands-on Course
12, 13, 14 & 15 May 2020, London

QbD and Lifecycle Management of Analytical Methods
21 & 22 May 2020, London

Stability Testing in Pharmaceutical Development and Manufacture
8 & 9 June 2020 London

HPLC Analytical Method Development and Validation
22 & 23 June 2020 London

HPLC Troubleshooting 24 June 2020 London

Tablet Compaction Analysis and how to improve your products
26 June 2020 and 19 November 2020 London

Pharmaceutical Packaging – an introductory course
25 & 26 June and 30 November & 1 December 2020 London

Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
14 & 15 September 2020 London

Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs
16 & 17 September 2020 London

Powder Technology for Pharmaceutical Development and Manufacturing
23, 24 & 25 September 2020 London

Pharmaceutical Dissolution Testing – a Hands-on Course
13, 14, 15 & 16 October 2020 London

Parenteral Products
tba 2020 London

Pharmaceutical Granulation and Compression
tba 2020 London

GMP Auditor Training for Quality Systems
tbc November 2020 London

Development of Stability-Indicating HPLC Methods
11c November 2020 London

HPLC Analytical Method Development and Validation
9 & 10 November 2020 London

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices
tbc 2020 London

Pharmacokinetics in Drug Development - an integrated approach
23 & 24 November 2020 London