ORGANISATION

Attendance Fee

750 € Regular

500 € Member of AGAH, EUFEMED
or Junior Scientist up to the age of 30

The participation fee is per person. Please note, according to §4 para 22 German turnover tax law, registration and workshop fees are exempt from VAT. Registration fees are charged and collected on behalf of AGAH e. V. All bookings are subject to change.

Registration Deadline: September 18, 2024

WORKSHOP VENUE

SocraTec R&D GmbH
Im Setzling 35
61440 Oberursel (Germany)

REGISTRATION

CSi Hamburg GmbH
Goernestraße 30
20249 Hamburg (Germany)
Phone: +49 40 30770 300
e-Mail: agah-meetings@csihamburg.de

CONTACT

Arbeitsgemeinschaft für angewandte Humanpharmakologie (AGAH) e.V.
Office: Goernestraße 30
20249 Hamburg (Germany)
Phone: +49 40 30772097
e-Mail: info@agah.eu
Web: www.agah.eu · www.studynurse.de

Registration Link
https://forms.office.com/e/CYZ008p76M

Programme subject to modifications, status October 2023

CONTENT

Pharmacokinetics – prerequisite and at the same time "door opener" for understanding pharmacology!

This workshop, developed by experienced specialists from industry, CRO and consultancy, offers an entrée to physiological background, measures, and characteristics of pharmacokinetics. It helps to understand study design and evaluation of PK studies and the conclusions drawn from the results.

The workshop has been developed for clinical investigators, project leaders, project managers and monitors as well as PhD students in industry, hospitals, university and CROs. The knowledge obtained in this applied introductory course helps beginners in pharmacokinetics obtaining the basic knowledge and scientific background for professional handling, evaluation, and interpretation of PK data.

FACULTY

Dr. Stephan Glund
Head of Clinical Pharmacology CREA
Boehringer Ingelheim Pharma GmbH & Co. KG
Biberach (Germany)

Dr. Roland Heinig
(formely) Clinical Pharmacology
Bayer AG, Pharmaceuticals
Wuppertal (Germany)

Dr. Joachim Höchel
Clinical Pharmacology
Bayer AG, Pharmaceuticals
Berlin (Germany)

Dr. Frank Runge
Clinical Pharmacology Lead
Boehringer Ingelheim Pharma GmbH & Co. KG
Biberach (Germany)

Helmut Schütz
BEBAC – Consultancy Services for Bioequivalence and Bioavailability Studies
Vienna (Austria)

Dr. Ralph-Steven Wedemeyer
Advisor Biopharmaceutics;
Head of Pharmaceutical Technology
SocraTec R&D GmbH
Oberursel (Germany)

AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

APPLIED COURSE INTRODUCTION INTO BASIC PRINCIPLES OF CLINICAL PHARMACOKINETICS

Preliminary Programme

OCTOBER 1-2, 2024
OBERURSEL (GERMANY)

PROGRAMME · DAY 1 · October 1, 2024

08:00 Registration

08:30 **Welcome and introduction** of participants and speakers
Joachim Höchel, Berlin; Barbara Schug, Oberursel

08:40 **Introduction into basic terms and principles of Pharmacokinetics (PK)**
Joachim Höchel, Berlin

09:00 **Human physiology: what you should know to better understand pharmacokinetics**
An overview of physiological characteristics being of (PK)-relevance for ***A***bsorption, ***D***istribution, ***M***etabolism and ***E***limination (**ADME**)
Roland Heinig, Wuppertal

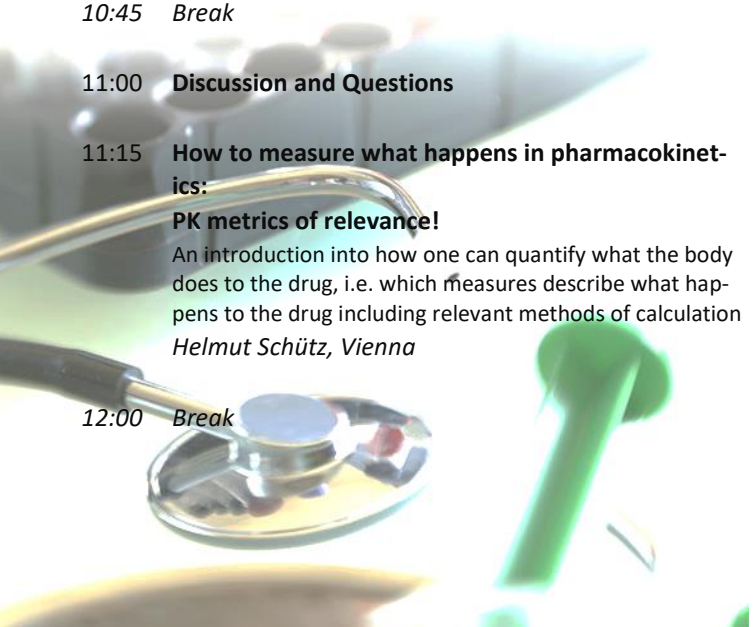
09:45 **In vitro ADME & preclinical PK**
Description of in vitro ADME parameters, such as Cytochrome P450 & drug transporter inhibition, drug absorption, plasma protein binding, and metabolic clearance; explanation of preclinical animal PK results and their translation to the human situation
Frank Runge, Biberach

10:45 Break

11:00 **Discussion and Questions**

11:15 **How to measure what happens in pharmacokinetics:**
PK metrics of relevance!
An introduction into how one can quantify what the body does to the drug, i.e. which measures describe what happens to the drug including relevant methods of calculation
Helmut Schütz, Vienna

12:00 Break



PROGRAMME · DAY 1 · October 1, 2024

13:00 **Human PK studies I: bioequivalence, food interaction and drug-drug-interaction studies**
Presentation of basic principles and design features such as choice of dosing, treatment and sampling schedule, evaluation approaches as well as population characteristics
Joachim Höchel, Berlin

14:15 Break

14:30 **Human PK studies II: Special populations characteristics considering liver, kidney and age**
Assessment of factors that relevantly impact PK in patients in adequately designed clinical trial considering authorities requirements
Roland Heinig, Wuppertal

16:00 Break

16:15 **Hands-on clinical PK – the practical exercise:**
How to design your PK program? An exercise with the goal to plan your own clinical PK program based on a preclinical data set
All

17:30 **Discussion and Questions**

18:00 **End of Day 1 Workshop Program**

18:15 **Option of individual consultation of the speakers**
Participants are invited to consult individual speakers if they have specific questions/case studies they wish to discuss with an expert.

PROGRAMME · Day 2 · October 2, 2024

08:30 **Introduction to biologics: what you should know to understand their pharmacokinetics**
An overview of their molecular characteristics which interfere with pharmacokinetics – which types, characteristics and differences are of relevance
Stephan Glund, Biberach

09:00 **Human PK – What's different in biologics?**
An introduction into bioanalytical methods, antibody development and their assessment, specificities in ADME, TMDD, immunogenicity, drug-drug interaction and comparability
Stephan Glund, Biberach

10:15 Break

10:30 **Human PK studies III: interplay between biopharmaceutics and absorption**
What you should know about galenics and biopharmaceutics to understand the interplay between formulation principles and pharmacokinetics
Ralph-Steven Wedemeyer, Oberursel

11:30 **Discussion and Questions**

12:00 Break

13:00 **Human PK studies IV: Human drug metabolism**
How to determine the overall pathways of metabolism and excretion of an investigational drug and how to use these results in the context of drug safety (MIST, DDI).
Frank Runge, Biberach

13:45 **Pitfalls in BA/BE**
Attempts in beating Murphy's law: Learnings from failures in study design, bioanalytics and statistics
Helmut Schütz, Vienna

14:30 Break

14:45 **Where all ends meet**
- PK information in the label
Review of a PK program
– What, When, How – and Why?
All

16:00 **End of Workshop**