FACULTY Part I & II

Dr. Sybille Baumann
CRS Berlin GmbH, Berlin/Germany

Dr. Antje Blank
University Medical Center Heidelberg/Germany

Dr. Kerstin Breithaupt-Grögler
kbr - clinical pharmacolgy services, Frankfurt/Main/Germany

Dr. Martin Coenen
University Medical Center Bonn/Germany

Dr. Katharina Erb-Zohar
clinphase, Hanau/Germany

Dr. Karin Göhler
Grünenthal GmbH, Aachen

Christian Hinze
medcom drug development services GmbH, Rheinau/Germany

Dr. Andreas Kovar
Sanofi-Aventis Deutschland GmbH, Frankfurt/Main/Germany

Dr. Stephanie Plassmann
PreClinical Safety (PCS) Consultants Ltd, Basel/Switzerland

FACULTY Part I & II

Dr. Jens Rengelhausen
Grünenthal GmbH, Aachen/Germany

Dr. Barbara Schug
SocraTec R&D GmbH, Oberursel/Germany

Prof. Dr. Hildegard Sourgens
Consultant, Munich/Germany

Dr. Jörg Täubel
Richmond Pharmacology Ltd, Tooting/United Kingdom

Dr. Wolfgang Timmer
Inamed GmbH, Gauting/Germany

Dr. Manfred Wargenau
M.A.R.C.O., Düsseldorf/Germany

Prof. Dr. Georg Wensing
Bayer Pharma AG, Wuppertal/Germany

Dr. Michael Zühlsdorf
Merck KGaA, Darmstadt/Germany

INFORMATION

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

Date
Part I
30 November - 02 December 2016
Part II
01 February - 03 February 2017

Fees
Part I (3 days) **or** Part II (3 days)

1.100 EUR Member*
1.450 EUR Non Member

Part I **and** Part II (2x3 days)

1.900 EUR Member*
2.500 EUR Non Member

*of AGAH, AHPPI, BAPU, CPI, ACCP, DGPharMed, DGKliPha

Special fees for students are available on request.

Minimum number of participants 10 guests
Registration Deadline Part I: 14/11/2016
Registration Deadline Part II: 16/01/2017

This course will be accredited by the Landesärztekammer, participants will be awarded ”Fortbildungspunkte”.

CONTACT AND FURTHER INFORMATION

AGAH e.V.
Association for Applied Human Pharmacology (AGAH) e.V.
Office: Goernestraße 30
20249 Hamburg
Phone: +49 (0)170 78 444 38
e-Mail: info@agah.eu
http://www.agah.eu

Registration
CSi Hamburg GmbH
Goernestraße 30
20249 Hamburg (Germany)
Phone: +49 (0)40 30 770 300
Telefax: +49 (0)40 30 770 301
E-Mail: agah-meetings@csihamburg.de

Registration-form Download
http://www.csioffice.de/_download/AGAH/Registration.pdf

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

Part II - Register now!
www.agah.eu

INTRODUCTORY COURSE

IN EXPLORATORY MEDICINES DEVELOPMENT

PART II

01 FEBRUARY - 03 FEBRUARY 2017

Oberursel, Germany

Announcement

INTRODUCTION AND LEARNING OUTCOMES

This course addresses postgraduates in life sciences interested in early clinical development of medicinal products. Two training parts of 3 days each provide a concise overview on Human Pharmacology / Translational Medicine spanning from non-clinical pharmacology and toxicology over first-in-man studies to proof-of-concept clinical trials.

Learning Outcomes

On successful completion of Part II, students should be able to demonstrate an understanding / knowledge of the following:

- nonclinical pharmacology and toxicology
- molecular basis of drug actions
- allometric scaling and dose proportionality assessments based on characteristic PK data
- defining pharmacodynamic (PD) endpoints and biomarkers
- differentiating between primary and secondary PK and PD endpoints
- How to design an early clinical pharmacology development plan
- planning and management of a first-in-man trial
- principles of data management and information flow
- principles of reporting and publication
- principles of medical statistics
- characteristic issues involved in the development of biologicals and biosimilars

programme modifications reserved

Day 1 · WEDNESDAY, 01 February 2017

09:00 - 09:15	Introduction of faculty and participants
09:15 - 09:30	Overview on Part II training course
09:30 - 11:00	**Molecular basis of drug action:** Receptor pharmacology, agonists, antagonists, second messengers, enzymes, regulatory proteins, transcription factors, cellular sites of drug actions *Dr. M. Coenen*
11:00 - 11:15	Break
11:15 - 13:00	**Pharmacodynamic endpoints and biomarker:** Cardiovascular, CNS, diabetes, immunology, challenging substances, stress tests, cardiac safety / QTc, how to assess proof of concept (PoM, PoC) *Dr. J. Rengelshausen or Dr. M. Zühlsdorf*
13:00 - 14:00	Break
14:00 - 17:30	**Assessment of non-clinical data and risk as prerequisites before administration to man:** Compound selection, early in vivo studies including primary and secondary pharmacodynamics and -kinetics, safety pharmacology, general toxicology in various species (rodents, non-rodents) including NOEL/NOAEL and MTD, toxicokinetics, genotoxicity, immunotoxicity, local tolerance, phototoxicity *Dr. S. Plassmann or Prof. Dr. H. Sourgens*
17:30 - 17:45	Break
17:45 - 18:45	**How to determine a safe starting dose for first-in-human?** Key safety parameters, presentation of case studies *Dr. S. Plassmann*

Day 2 · THURSDAY, 02 February 2017

08:45 - 09:45	**How to determine a safe starting dose for first-in-human?** Key safety parameters, presentation of case studies *Dr. S. Plassmann*
09:45 - 10:00	Break
10:00 - 12:00	**Pharmacokinetics III:** PK linearity / non-linearity, dose proportionality assessments, allometric scaling, 14C-studies, absorption half-life, flip-flop kinetics, protein binding, biopharmaceutics classification system *Dr. A. Kovar*
12:00 - 12:45	**Stop dose escalation or continue dosing?** Case study developed in break-out groups *Dr. K. Erb-Zohar*
12:45 - 13:30	Break
13:30 - 14:15	**Stop dose escalation or continue dosing?** Case study developed in break-out groups *Dr. K. Erb-Zohar*
14:15 - 14:30	Break
14:30 - 18:00	**How to design an early clinical pharmacology development program?** Basic concepts of FIM trial and early clinical pharmacology trials supporting early clinical development and decision making. Case study developed in break-out groups *Dr. K. Göhler*

Day 3 · FRIDAY, 03 February 2017

08:45 - 09:15	**Data management:** Principles, electronic / paper CRFs, queries, data cleaning, data base closure *Dr. M. Wargenau*
09:15 - 09:45	**Reporting and publication:** Flow of information, types of reports, guidelines, abstracts and full papers *Dr. K. Breithaupt-Grögler*
09:45 - 10:00	Break
10:00 - 12:45	**Analysis of early exploratory development studies - principles of medical statistics:** Differences between treatments regarding biomarkers, pharmacokinetic / -dynamic effects, safety, parametric vs. non-parametric analysis, t-tests, repeated measures ANOVA, parametric vs. non-parametric analysis, Chi-square, Fisher‘s exact *Dr. M. Wargenau*
12:45 - 13:45	Break
13:45 - 15:45	**Introduction to biologicals and biosimilars** *Prof. Dr. H. Sourgens*
15:45 - 16:30	**Mandatory Test on Part II** 50% of questions must be correctly answered to pass test and receive a certificate
16:30 - 17:00	Feed back and end of Part II