

FACULTY Part I & II

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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, DGKIIPha

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".

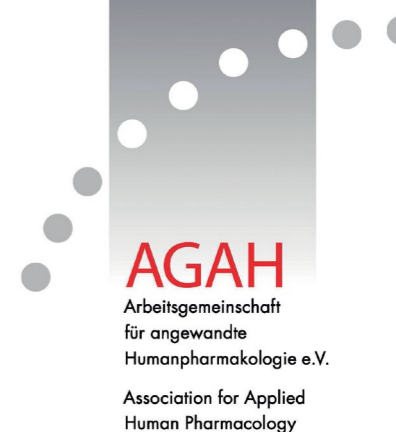
CONTACT AND FURTHER INFORMATION

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



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

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 <i>Dr. M. Coenen</i>
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) <i>Dr. J. Rengelshausen or Dr. M. Zühlendorf</i>
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 <i>Dr. S. Plassmann or Prof. Dr. H. Sourgens</i>
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 <i>Dr. S. Plassmann</i>

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 <i>Dr. S. Plassmann</i>
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 <i>Dr. A. Kovar</i>
12:00 - 12:45	Stop dose escalation or continue dosing? Case study developed in break-out groups <i>Dr. K. Erb-Zohar</i>
12:45 - 13:30	Break
13:30 - 14:15	Stop dose escalation or continue dosing? Case study developed in break-out groups <i>Dr. K. Erb-Zohar</i>
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 <i>Dr. K. Göhler</i>

Day 3 · FRIDAY, 03 February 2017

08:45 - 09:15	Data management: Principles, electronic / paper CRFs, queries, data cleaning, data base closure <i>Dr. M. Wargenau</i>
09:15 - 09:45	Reporting and publication: Flow of information, types of reports, guidelines, abstracts and full papers <i>Dr. K. Breithaupt-Grögler</i>
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 <i>Dr. M. Wargenau</i>
12:45 - 13:45	Break
13:45 - 15:45	Introduction to biologicals and biosimilars <i>Prof. Dr. H. Sourgens</i>
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