FACULTY Part I & II

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Die Inhalte der Fortbildungsmaßnahme sind produkt- und/oder dienstleistungsneutral gestaltet. Potenzielle Interessenkonflikte der Referierenden werden in einer Selbstauskunft gegenüber den Teilnehmenden offen gelegt werden. Der Introductory Course Part I + II ist eine Eigenveranstaltung der AGAH e. V. und wird nicht durch Sponsoring finanziert. Die Höhe der Gesamtaufwendungen beträgt ca. 20.000 € für die Ausrichtung.

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. 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

INFORMATION

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

Date
Part II
31 March - 3 April 2020

Fees
Part II (4 days)

1.100 EUR Member*
1.450 EUR Non Member

Part I **and** Part II

1.900 EUR Member*
2.500 EUR Non Member

*of AGAH, AHPPI, BAPU, AFPT-CPI, ACCP, EUFEMED

Special fees for students are available on request.

Minimum number of participants 10 guests
Registration deadline Part II: 16/3/2020

CONTACT AND FURTHER INFORMATION

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

INTRODUCTORY COURSE

IN EXPLORATORY MEDICINES DEVELOPMENT

PART II

31 March - 3 APRIL 2020

Oberursel, Germany

PharmaTrain MASTERING MEDICINES DEVELOPMENT COURSE RECOGNITION

EUFEMED

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 pro-of-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

This AGAH course meets the standards for high-quality postgraduate education and training in Medicines Development established by PharmaTrain and has been awarded a PharmaTrain Recognition. The course was accredited 3 ECTS (Parts I plus II).

programme modifications reserved

Day 1 · TUESDAY, 31 March 2020

10:00 - 10:15	Introduction of faculty and participants
10:15 - 10:30	Overview on Part II training course
10:30 - 12:00	**Molecular basis of drug action:** Receptor pharmacology, agonists, antagonists, second messengers, enzymes, regulatory proteins, transcription factors, cellular sites of drug actions *Martin Coenen*
12:00 - 13:00	Break
13:15 - 14:45	**Pharmacodynamic endpoints and biomarker:** Biomarkers for stratified medicine, companion diagnostics and proof of concept; biomarkers and PD endpoints in oncology, diabetes, car diovascular diseases, cardiac safety and in pain *Jens Rengelshausen* *Michael Zühlsdorf*
14:45 - 15:00	Break
15:00 - 18:30	**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, safety ratio, toxicokinetics, genotoxicity, immunotoxicity, local tolerance, phototoxicity *Stephanie Plassmann*
18:30 - 20:30	**Get together/ formation of break-out groups**

Day 2 · WEDNESDAY, 1 April 2020

09:00 - 10:45	**Assessment of non-clinical data and risk as prerequisites before administration to man (continuation of Day 1)** *Stephanie Plassmann*
10:45 - 11:00	Break
11:00 - 11:30	**The revised EMA guideline on early phase clinical trials – key elements** Kerstin Breithaupt-Grögler
11:30 - 12:45	**How to determine a safe starting dose for first-in-human?** Key safety parameters, case study developed in break-out groups *Stephanie Plassmann*
12:45 - 13:45	Break
13:45 - 14:45	**How to determine a safe starting dose for first-in-human?** Presentations of case study *Stephanie Plassmann*
14:45 - 15:00	Break
15:00 - 15:30	**Quiz on essential terms:** questions and answers provided by the audience *Kerstin Breithaupt-Grögler*
15:30 - 15:45	Break
15:45 - 17:15	**Pharmacokinetics III:** PK linearity / non-linearity / dose proportionality assessments, biopharmaceutics classification system (BCS), absorption half-life, flip-flop kinetics, protein binding, 14C-studies (mass-balance studies), allometric scaling *Andreas Kovar*

Day 3 · THURSDAY, 2 April 2020

09:00 - 10:00	**Stop dose escalation or continue dosing?** Case study developed in break-out groups *Katharina Erb-Zohar*
10:00 - 10:15	Break
10:15 - 11:00	**Stop dose escalation or continue dosing?** Presentations of case studies *Katharina Erb-Zohar*
11:00 - 12:15	**How to design a first-in-human trial?** Development of case study in break-out groups *Karin Göhler*
12:15 - 13:15	Break
13:15 - 14:00	**How to design a first-in-human trial?** Presentations of case study *Karin Göhler*
14:00 - 14:15	Break
14:15 - 16:00	**How to proceed from single ascending dose to multiple ascending dose?** Assessment and evaluation of SAD safety and PK data, integrated protocols versus consecutive trials. *Karin Göhler*
16:00 - 16:15	Break
16:15 - 18:00	**How to design an early clinical pharmacology development program?** Basic concepts of early phase trials supporting early clinical development and decision making *Karin Göhler*

Day 4 · FRIDAY, 3 April 2020

08:45 - 09:15	**Flow of information and reporting of trial data** *Kerstin Breithaupt-Grögler*
09:15 - 09:45	**Data management:** Principles, electronic / paper CRFs, queries, data cleaning, data base closure *Manfred Wargenau*
09:45 - 10:00	Break
10:00 - 10:45	**Monitoring and Auditing** - An essential tool to ensure credibility of data *Christian Hinze*
10:45 - 11:00	Break
11:00 - 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 *Manfred Wargenau*
12:45 - 13:30	Break
13:30 - 14:15	**Analysis of early exploratory development studies** - principles of medical statistics (continued) *Manfred Wargenau*
14:15 - 16:00	**Introduction to biologicals and biosimilars** *tba*
16:00 - 16:45	**Mandatory Test on Part II** (50% of questions must be correctly answered to pass test and receive a certificate)
16:45 - 17:00	Feed back and end of Part II