FACULTY Part I & II

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Die Inhalte der Fortbildungsmaßnahme sind produkt- und/oder dienstleistungs-neutral 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

Dr. Wolfgang Timmer
Inamed GmbH, Gauting/Germany

Dr. Manfred Wargenau
M.A.R.C.O. GmbH & Co. KG, Düsseldorf/Germany

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

PD Dr. Michael Zühlsdorf
Merck Healthcare KGaA, Darmstadt/Germany

INFORMATION

Venue: Online Course @ ‚Microsoft Teams' -you will receive your personal login data-

Requirement: Please download the Desktop App when you are ask

Date: Part II
17-18 September 2020
21-22 September 2020

Fees: Part II (4 days)

1.100 EUR Member*
1.450 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: 10/8/2020

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

-ONLINE COURSE-

17-18 September and

21-22 September 2020

PharmaTrain MASTERING MEDICINES DEVELOPMENT COURSE RECOGNITION

EUFEMED EUROPEAN FEDERATION FOR EXPLORATORY MEDICINES DEVELOPMENT

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 · THURSDAY, 17 September 2020

from 08:45	Dial-in
09:00 - 09:15	Introduction of faculty and participants
09:15 - 10:45 5‘ break after 45‘	**Molecular basis of drug action:** Receptor pharmacology, agonists, antagonists, second messengers, enzymes, regulatory proteins, transcription factors, cellular sites of drug actions *Martin Coenen*
10:45 - 11:00	Break
11:00 - 13:00 5‘ break after 60‘	**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*
13:00 - 13:45	Break
13:45 - 17:30 5‘ break every 60‘ 15‘ break after 120‘	**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*

Day 2 · FRIDAY, 18 September 2020

09:00 - 11:00 5‘ break after 60‘	**Assessment of non-clinical data and risk as prerequisites before administration to man** (continuation of Day 1) *Stephanie Plassmann*
11:00 - 11:15	Break
11:15 - 11:45	**The revised EMA guideline on early phase clinical trials – key elements** *Kerstin Breithaupt-Grögler*
11:45 - 13:00	**How to determine a safe starting dose for first-in-human?** Key safety parameters, case study developed in break-out groups *Stephanie Plassmann*
13:00 - 13:45	Break
13:45 - 15:15	**How to determine a safe starting dose for first-in-human?** Presentations of case study *Stephanie Plassmann*
15:15 - 15:30	Break
15:30 - 16:15	**Stop dose escalation or continue dosing?** Introduction to case study *Kerstin Breithaupt-Grögler*
Mandatory Homework	**Stop dose escalation or continue dosing?** Case study developed in break-out groups

Day 3 · MONDAY, 21 SEPTEMBER 2020

09:00 - 10:00	**Stop dose escalation or continue dosing?** Presentation of case studies *Kerstin Breithaupt-Grögler* *Jens Rengelshausen*
10:00 - 11:30	**How to design an early clinical pharmacology development program?** Basic concepts of early phase trials supporting early clinical development and decision making: how to design the first-in-human trial? how to proceed from single to multiple ascending dose? which questions needs to be answered prior to further clinical development?, including case study *Jens Rengelshausen* *Kerstin Breithaupt-Grögler*
11:30 - 11:45	Break
11:45 - 13:15	**How to design an early clinical pharmacology development program?** (continued) *Kerstin Breithaupt-Grögler* *Jens Rengelshausen*
13:15 - 14:00	Break
14:00 - 15:00	**Bioequivalence trials:** How to do it right – planning a successful BE trial *Barbara Schug*
15:00 - 15:15	**Q&A session regarding method validation** (pre-reading of slides required)
15:15 - 15:30	Break
15:30 - 17:15 5‘break after 60‘	**Pharmacodynamic endpoints and biomarker:** Biomarkers for stratified medicine, companion diagnostics and proof of concept; biomarkers and PD endpoints in oncol logy, diabetes, cardiovascular diseases, cardiac safety and in pain *Jens Rengelshausen*

Day 4 · TUESDAY, 22 SEPTEMBER 2020

09:00 -10:00	**Data management:** Principles, electronic / paper CRFs, queries, data cleaning, data base closure *Manfred Wargenau*
10:00 - 10:15	Break
10:15 - 11:15	**Monitoring and Auditing** - An essential tool to ensure credibility of data *Christian Hinze*
11:15 - 11:30	Break
11:30 - 13:15 5‘ break after 60‘	**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*
13:15 - 14:00	Break
14:00 - 15:00	**Analysis of early exploratory development studies - principles of medical statistics** (continued) *Manfred Wargenau*
15:00 - 15:15	Break
15:15 - 15:30	**Q&A session regarding report writing** (pre-reading of slides required) *Kerstin Breithaupt-Grögler*
15:30 - 17:00	**Introduction to biologicals and biosimilars** *Barbara Schug*
17:00 - 17:15	**Feed back and end of Part II**
17:30 - 18:30	**Mandatory Test on Part II via Survey** (within 1 hour, 60 % of questions must be correctly answered to pass test and receive a certificate)