FACULTY Part I & II

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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.

INFORMATION

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

Requirement
Please download the Desktop App
when you are asked

Date
Part II
11-12 November 2021
15-16 November 2021

Fees
Part II (4 days)

1.000 EUR Member*
1.350 EUR Non Member

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

Special fees for students are available on request.

Minimum number of participants 10 guests
Registration deadline Part II: 10/28/2021

Registration (engl.)

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-

11-12 November and

15-16 November 2021

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, 11 November 2021

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, 12 November 2021

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 *Katharina Erb-Zohar*
Mandatory Homework	**Stop dose escalation or continue dosing?** Case study developed in break-out groups

Day 3 · MONDAY, 15 November 2021

09:00 - 10:00	**Stop dose escalation or continue dosing?** Presentation of case studies *Katharina Erb-Zohar*
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* *Michael Zühlsdorf*

Day 4 · TUESDAY, 16 November 2021

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 *tba*
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)