

FACULTY Part I & II

Dr Sybille Baumann
CRS Berlin GmbH, Berlin/Germany

PD Dr Antje Blank
University Medical Center Heidelberg/Germany

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

Dr Martin Coenen
University Medical Center Bonn/Germany

Dr Katharina Erb-Zohar
clinphase, Schotten/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 Rengelshausen
Grünenthal GmbH, Aachen/Germany

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

Dr Wolfgang Timmer
Nuvisan 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 asked

Date **Part II**
26 January - 2 February 2023

Fees **Part II (3 full days, 2 half 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: 1/18/2023

CONTACT AND FURTHER INFORMATION

AGAH e.V. Association for Applied
Human Pharmacology (AGAH) e.V.
Office: Goernestraße 30
20249 Hamburg
Phone: +49 (0)40 30772097
email: info@agah.eu
<http://www.agah.eu>

Registration CSi Hamburg GmbH
Goernestraße 30
20249 Hamburg (Germany)
Phone: +49 (0)40 30770300
email: agah-meetings@csihamburg.de



AGAH

Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

**INTRODUCTORY COURSE
IN EXPLORATORY MEDICINES DEVELOPMENT**

**PART II
-ONLINE COURSE-**

26 January - 2 February 2023

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 angegebenen Uhrzeiten für Themenkomplexe und Pausen sind Richtwerte. Anpassungen im Tagesverlauf erfolgen nach Bedarf. Die Höhe der Gesamtaufwendungen beträgt ca. 20.000 € für die Ausrichtung.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
COURSE RECOGNITION

EU FEMED
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 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

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).

Day 1 · THURSDAY, 26 January 2023

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 <i>Martin Coenen</i>
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 <i>Andreas Kovar</i>
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 <i>Stephanie Plassmann</i>

Day 2 · FRIDAY, 27 January 2023

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) <i>Stephanie Plassmann</i>
11:00 - 11:15	Break
11:15 - 11:45	The revised EMA guideline on early phase clinical trials – key elements <i>Kerstin Breithaupt-Grögler</i>
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 <i>Stephanie Plassmann</i>
13:00 - 13:45	Break

13:45 - 15:15	How to determine a safe starting dose for first-in-human? Presentations of case study <i>Stephanie Plassmann</i>
15:15 - 15:30	Break
15:30 - 16:15	Stop dose escalation or continue dosing? Introduction to case study <i>Katharina Erb-Zohar</i>
Mandatory Homework	Stop dose escalation or continue dosing? Case study developed in break-out groups

Day 3 · TUESDAY, 31 January 2023

09:00 - 10:00	Stop dose escalation or continue dosing? Presentation of case studies <i>Katharina Erb-Zohar</i>
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 <i>Jens Rengelshausen</i> <i>Kerstin Breithaupt-Grögler</i>
11:30 - 11:45	Break
11:45 - 13:15	How to design an early clinical pharmacology development program? (continued) <i>Kerstin Breithaupt-Grögler</i> <i>Jens Rengelshausen</i>

Day 4 · WEDNESDAY, 1 February 2023

14:00 - 15:00	Bioequivalence trials: How to do it right – planning a successful BE trial <i>Barbara Schug</i>
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 oncology, diabetes, cardiovascular diseases, cardiac safety and in pain <i>Jens Rengelshausen</i> <i>Michael Zühlsdorf</i>
---------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Day 5 · THURSDAY 2 February 2023

09:00 -10:00	Data management: Principles, electronic / paper CRFs, queries, data cleaning, data base closure <i>Manfred Wargenau</i>
10:00 - 10:15	Break
10:15 - 10:45	Clinical trial report - <i>Kerstin Breithaupt-Grögler</i>
10:45 - 11:00	Break
11:00 - 12:45 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 <i>Manfred Wargenau</i>
12:45 - 13:30	Break
13:30 - 14:45	Analysis of early exploratory development studies - principles of medical statistics (continued) <i>Manfred Wargenau</i>
14:45 - 15:00	Break
15:00 - 16:30	Introduction to biologicals and biosimilars <i>Barbara Schug</i>
16:30 - 16:45	Feed back and end of Part II Mandatory Test on Part II via Survey (60 % of questions must be correctly answered to pass test and receive a certificate)