The Basics of Human Pharmacology

This 2 x 2½ day course provides a basic training in Human Pharmacology and is addressed to postgraduates in life sciences interested in early clinical development of medicinal products.

Learning Outcomes

On successful completion of Part 1 of this course, students should be able to demonstrate an understanding / knowledge of the following:

- principal steps in drug development from compound selection to marketing application, i.e., the pharmaceutical, non-clinical and clinical development
- pertinent issues involved in the undertaking of early clinical research
- management of drug safety issues
- regulation of medicines in Europe
- development and review of compound-specific information to ensure adherence to scientific, medical, ethical, and legal provisions
- selection of the appropriate trial population
- principles of study design, protocol submission and conduct
- relevance of formulation properties and in vitro characteristics of the trial medication for study design and study planning
- basics of GMP-related issues for acceptance of the IMPD
- pharmacokinetic and pharmacodynamic principles of drug effects

Flyer v2.0

Venue Part 1:

Seminarzentrum und Gästehaus der
SRH Business Academy GmbH
Bonhoefferstraße 12
69123 Heidelberg

Dates: Part 1 - 14 to 16 November 2013
Part 2 - 13 to 15 February 2014

Fees: Part 1 or Part 2 (2½ days)

1.000,00 €	members*
1.250,00 €	non-members
750,00 €	students

Part 1 and 2 (2 x 2½ days)

1.750,00 €	members
2.000,00 €	non-members
1.300,00 €	students

* AGAH, CPI, AHPPI, BAPU, DGPharMed, DGKLiPha

This meeting is accredited by the Landesärztekammer, participants will be awarded ”Fortbildungspunkte”.

Registration | Workshop Office:

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AGAH

Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

THE BASICS OF HUMAN PHARMACOLOGY

An Introduction to the basics of human pharmacology and the practical, regulatory and ethical aspects of early phase clinical trials

PART 1

14 TO 16 NOVEMBER 2013
HEIDELBERG

Second Announcement

14 NOVEMBER 2013

13:00 **Registration**

14:00 **Introduction of faculty and participants**

14:30 **Overview of Part 1**

14:45 **Clinical drug development – scientific /methodological aspects**
(from compound selection to submission: preclinical studies, evaluation of toxicity, clinical development, pharmacokinetics, pharmacodynamics, first-in-man, Phase 0, Phases I to III, exploratory vs. confirmatory trials, marketing application, Phase IV, non-interventional studies / post-marketing surveillance, epidemiological studies)
K. Breithaupt-Grögler, G. Wensing

16:30 **Break**

17:00 **Clinical drug development - regulatory and ethical environment**
(Declaration of Helsinki, EU-Directives, ICH-Guidelines, GCP, AMG, local European law [Switzerland, Austria, UK, Netherlands], trial authorisation: ethics committee favourable opinion and competent authority approval, submission and marketing authorisation, pharmacovigilance, abbreviations)
K. Breithaupt-Grögler, G. Wensing

19:00 **End of Day 1**

15 NOVEMBER 2013

08:30 **Overview on preclinical development from early compound selection to submission**
(in silico, in vitro assays, early in vivo studies incl. primary and secondary pharmacodynamics and kinetics, safety pharmacology, genotoxicity, general and reproductive toxicity in various species [rodents, non-rodents] incl. NOEL/NOAEL and MTD, carcinogenicity, special studies, ICH M3 Guideline)
S. Plassmann, H. Sourgens

10:45 **Break**

11:15 **Designing a human pharmacology trial**
(populations, number of patients in Phase I, randomised, controlled, placebo, staggered timing, cross-over, parallel-group, single-blind, double-blind, dose-escalation, single dose, multiple dose, drug-drug interaction, drug-food interaction, bioavailability, bioequivalence, adaptive designs)
W. Timmer

13:00 **Break**

14:00 **Break-out groups: What do we need to start a clinical trial in humans?**
All

14:30 **Competent authority approval and ethics committee opinion**
(IB/IMPD, trial protocol / substantial amendment, informed consent, qualification of investigator / staff / trial site, submission, Module 1, Module 2)
I. Klingmann, C. Hinze

15:45 **Break**

16:00 **Selection of trial population, inclusion / exclusion criteria in early drug development**
(healthy subjects, symptomatic subjects, patients [proof of concept], children, elderly, gender, women of childbearing potential, ethnicities, cultural differences)
K. Erb-Zohar, J. Täubel

17:30 **End of Day 2**

16 NOVEMBER 2013

08:30 **Trial medication**
(drug substance / product, route of administration, formulations / drug-food interaction, specific aspects of preparation / administration / storage in Phase I, drug accountability, test / reference therapy, blinding, double-dummy, challenging substances, labelling, stabilisation, IMPD information, Non-IMPD medication, code breaking envelopes / emergency unblinding, release process according to ANNEX 13)
B. Schug

10:00 **Break**

10:15 **Biomarkers, pharmacodynamic endpoints and models**
(biomarker definitions and examples from oncology, diabetes, cardiovascular and cardiac safety; pharmacodynamic models e.g. for pain)
M. Zühlsdorf, J. Rengelshausen

12:00 **Break**

13:00 **Quiz: Human Pharmacology Terms Part I**

13:15 **Pharmacokinetics I:**
ADME, drug-drug interaction, drug-food interaction, bioequivalence / bioavailability, steady state, accumulation factors
A. Kovar, M. Zühlsdorf

14:30 **Break**

14:45 **Pharmacokinetics II:**
pharmacogenetics / polymorphisms, pharmacometrics, PK/PD relationship
A. Kovar, M. Zühlsdorf

16:00 **Test on Part I contents**

16:30 **Feedback and end of Part I**