Seminar

FORUM
40 YEARS

Toxicology Summer School

Topics

- Toxicokinetics and drug–drug interaction
- Mutagenicity and genotoxicity
- Carcinogenicity
- Reproductive toxicity and safety pharmacology
- Immunogenicity
- Risk assessment and risk communication

Know-how for employees in
- **R&D**
- **Medical affairs**
- **Regulatory affairs**
- **Pharmacovigilance**

Your speakers

Prof Dr Michael Arand
Institute of Pharmacology and Toxicology, University of Zurich, SWITZERLAND

Dr Susanne Brendler-Schwaab
– requested –
Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr Niklas Czeloth
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, GERMANY

Dr Monika Chabicovsky
MC Toxicology Consulting GmbH, Vienna, AUSTRIA

Dr Hans-Joerg Martus
Novartis Institutes for BioMedical Research (NIBR), Basel, SWITZERLAND

21 - 23 August 2019 in Frankfurt

Your speakers

Prof Dr Michael Arand
University of Zurich, SWITZERLAND

Professor of Toxicology and Pharmacology, EUROTOX-registered toxicologist

Dr Susanne Brendler-Schwaab
Senior Expert Regulatory Affairs, Bonn, GERMANY

She is also an expert in genotoxicity and photogenotoxicity.

Dr Monika Chabicovsky
Managing Director, MC Toxicology Consulting GmbH, Vienna, AUSTRIA

She is a toxicologist and a trained expert in regulatory affairs.

Dr Niklas Czeloth
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, GERMANY

He is leading international drug development programmes at BI.

Dr Hans-Joerg Martus
Novartis Institutes for BioMedical Research (NIBR), Basel, SWITZERLAND

He heads the Genetic Toxicology and Photosafety unit.

Day 1: 10:00 -18:00

10:00

Pharmacokinetics and toxicokinetics
Prof Dr Michael Arand

- The mechanistic basis ADME (absorption, distribution, metabolism, excretion)
- Species differences
- Polymorphisms as the basis for interindividual variability
- Enzyme induction/inhibition as the basis for intraindividual variability
- Biological activity of metabolites
- In vitro versus in vivo studies – pros and cons

12:30 Lunch

13:45

Drug–drug interactions
Prof Dr Michael Arand

14:30

General principles
Dr Susanne Brendler-Schwaab

- In vivo/in vitro studies
- Acute versus chronic toxicity; single dose versus repeat dose toxicity
- Toxicological endpoints
- Upcoming changes in ICH guidelines for preclinical safety
- Additional ICH guidelines with non-clinical aspects

16:30 Coffee break

16:45

Toxicological studies in a regulatory affairs context
Dr Susanne Brendler-Schwaab

- Prerequisites for first-in-human studies

Your programme

Day 2: 09:00 -17:00

09:00

Mutagenicity and genotoxicity

Dr S. Brendler-Schwaab, Dr H.-J. Martus

- Test systems and test strategies
- ICH S2 – Guidance on Specific Aspects of Regulatory Genotoxicity Tests
- Guidance ICH M7 – Assessment and Control of DNA Reactive Impurities
- Case studies

11:30

Photosafety evaluation

Dr Susanne Brendler-Schwaab

12:15 Lunch

13:15

Carcinogenicity

Dr Hans-Joerg Martus

- Principles of carcinogenicity testing
- Regulatory guidances
- Transgenic animals
- Case studies

15:00 Coffee break

15:15

Reproductive toxicology

Dr Hans-Joerg Martus

- Principles of reproductive toxicity testing
- Regulatory guidances

16:00

Safety pharmacology

Dr Hans-Joerg Martus

- Disciplines of safety pharmacology
- Regulatory principles and guidelines
- Cardiovascular safety pharmacology

Day 3: 09:00 -16:00

09:00

Immunotoxicity

Dr Niklas Czeloth

- The principles of the ICH S8 guideline
- Points to consider in immunotox. studies
- Examples of immunotoxicology effects

11:15 Coffee break

11:30

Deviating from standard requirements: a reduced non-clinical programme

Dr Monika Chabicovsky

- Overview of a standard toxicological programme
- The value of publicly available data/ literature searches
- What is the 3Rs principle and when shall it be applied?
- Excursion: authority interactions/ scientific advice
- Case studies: when, why and how to skip In vivo studies

13:00 Lunch

14:15

Risk assessment and risk communication

Dr Monika Chabicovsky

- The dark side of speeding up the non-clinical development
- Examples that triggered changes in regulatory requirements
- Risk-based approach: ATMPs as an example

Toxicology Summer School

What you will learn

During this Summer School:

- you will build a solid toxicological know-how basis;
- you will get to know the essential toxicological modes of action and learn how to apply them to your products;
- you will receive good insights into the toxicological study programme and learn how it must be scheduled in drug development;
- you will be informed about the inclusion of toxicological data in the marketing authorisation dossier and the associated regulatory affairs duties.

Who should attend?

This Summer School addresses the need for solid toxicological know-how of employees in the pharmaceutical industry, particularly those in the following departments:

- Research and development
- Medical affairs
- Regulatory affairs
- Pharmacovigilance

Basic scientific/medical knowledge would be helpful, toxicological know-how is not expected.

Registration: service@forum-institut.de or fax +49 6221 500 555

Yes, I will attend the

☐ **Toxicology Summer School**

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

- **Registration: +49 6221 500-500**
- **Conference-No. 19 08 234**

- **Date/Venue:**
21 - 23 August 2019 in Frankfurt
Hotel Frankfurt Messe
Katharinenkreisel · 60486 Frankfurt
Tel. +49 69 70730-0 · Fax +49 69 70730-333

- **Fee:**
€ 2,390.00 (+German VAT) incl. course documentation (incl. free download) as well as mid-session refreshments, lunch and certificate.

- **Questions and information:**
Dr. Henriette Wolf-Klein
Department Manager Pharmaceuticals & Healthcare
Tel. +49 6221 500 680 · h.wolf-klein@forum-institut.de

- **Cancellation Policy:**
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