Toxicology Summer School

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

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 Monika Chabicovsky
MC Toxicology Consulting
GmbH, Vienna, AUSTRIA

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

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

21 - 23 August 2019 in Frankfurt
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 immunotoxicology 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
# 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.

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## 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.

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## 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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