



Toxicology Winter School

Topics

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

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
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

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 heading the pharmacology,
toxicology and DMPK activities for
the Biosimilar Projects 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

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 – 17:00

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

- The value of publicly available data/literature searches
- 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

15:30 Coffee break

15:45

Environmental risk assessment

Dr Monika Chabicovsky

What you will learn

During this Winter 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 Winter 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: formacion@qualitecfarma.com or tel. +34 91 372 83 99

Yes, I will attend the

Toxicology Winter School

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

■ **Registration: +34 91 372 83 99**

■ **Conference-No. 18 01 233**

■ **Date/Venue:**

23 – 25 January 2018 in Mannheim
Mercure Hotel Mannheim am Rathaus
F7,5 · 68159 Mannheim
Tel. +49 621 336990 · Fax +49 621 33699-2100

■ **Fee:**

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

■ **Questions and information:**

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Conference Manager (QualitecFarma)
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■ **Cancellation Policy:**

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