safescimet course 3.4 - Reproductive Toxicology

Key Questions Addressed

- Spermatogenesis and oogenesis
- Embryology
- Morphology of the male and female reproductive systems
- Timing of pregnancy (mouse, rat, rabbit, non-human primate, versus human)
- Perinatal development of metabolizing systems
- Pharmacokinetic aspects in reproductive toxicology
- Methods for examination of female/male fertility in animal models
- Regulatory aspects of tests on reproductive toxicology
- Drugs and pregnancy
- In vitro assays: advantages, disadvantages and validation

Feedback from the Previous Course

"I am looking forward to more courses and lectures on reproductive Pharmacology and Toxicology."
"Good balance between theory and practical exercises."

About safescimet

safescimet is a unique pan-European network of academia and pharmaceutical industry, which have joined forces to establish a comprehensive Modular Education and Training in Safety Sciences for medicines. The programme covers all aspects of safety in drug development, in order to fulfil the needs of drug safety scientists in the pharmaceutical industry, regulatory authorities and academia. The aim of the programme is to bridge crucial gaps in the education and training of scientists evaluating the safety of drug candidates and new medicines and to ensure that European drug safety scientists are at the forefront of their field.
The course Reproductive Toxicology and the other single courses of the safescimet programme provide new opportunities for Continuous Professional Development (CPD) and are part of European Master for Advanced Safety Sciences for Medicines degree at the University of Konstanz. The individual courses are clustered within five separate domains. Each domain deals with one or more specialised topics and contains from two to six single courses. Please visit www.safescimet.eu for details of the full course programme and confirmation of course dates.

Course Objectives

During embryo-fetal development xenobiotic substances can interfere with the "normal" development of the organism, while the effects and severity are dependent on the timing and developmental stage during which the exposure takes place. In contrast to other types of toxicity, interpretation of reproductive toxicity studies is more complicated and, due to the inclusion of a broad range of endpoints, requires a profound knowledge in order to detect any effects a new compound can have on mammalian reproduction. Additionally, it is essential to investigate and interpret these results in relation to all other pharmacological and toxicological data available. The reproductive toxicity of drugs is usually assessed with animal experiments, using the classical three "segment testing protocols". The course will also present newer alternative methods in reproductive toxicity testing such as the "whole-embryo-culture" or the embryonic stem cell test. An additional part of the lectures will discuss the authority guidelines.

Key Subjects Covered by the Course

- Morphology and physiology of the male and female reproductive tract
- Prenatal and postnatal development of mammalian organisms
- Standard testing for fertility impairment and developmental toxicity
- Developmental neurotoxicity/immunotoxicity
- Reproductive toxicity of selected drugs and workplace chemicals
- Relevance of maternal toxicity
- Pharmacokinetic issues in reproductive toxicology
- Endocrine disrupting chemicals
- Toxicogenomics in developmental toxicology
- Guidelines (ICH, OECD etc)

Target Audience

safescimet courses are open to all scientists and students from industry, academia and regulatory authorities, who need a broad comprehensive understanding of the drug development process with particular emphasis on safety. The applicant will normally possess an MSc degree in a Life Science discipline or equivalent. In addition, applicants are expected to have an at least one year working experience in a related discipline.

Why Join the Course

The on-site training of the course during the first week consists of five days with lectures, practical exercises, group work and discussions. This setup offers an intense and broad training with leading experts in their field and ample opportunities for lecturer-student interactions. The balance of academic, industry and regulatory teachers provides knowledge directly available to drug safety assessment, including dataset discussions from real case studies.

Learning Outcomes

On successful completion of the module, participants will understand basic reproduction-related pathological findings in a broader context, which will assist them in communicating with specialist pathologists. More specifically, participants will be able to

- have an appreciation of basic organ functions and their diverse response to toxicity
- know and understand the themes and major processes in organ/system toxicity
- relate the basics of molecular and physiological response of an organ/system to toxicant insult
- be aware of and be able to apply new technologies and methods available for evaluation of organ/system toxicology

- design experiments in order to assess and identify specific organ/system toxicity
- apply relevant parameters to detect organ/system toxicity in the preclinical and clinical setting with statistical methods for risk assessments

Course Programme

The first week of the course in Berlin consists of five days lectures, practical exercises, group work and discussions, provided by specialists from academia, pharmaceutical industry and regulatory authorities with diverse backgrounds on drug safety aspects.

On-site Training

Day 1	Morphology and physiology of mammalian reproductive tracts; Prenatal development
Day 2	Basics of reproductive toxicology
Day 3	Reproductive toxicology of selected drugs and workplace chemicals
Day 4	Evaluation of reproductive toxicology: in vitro/in vivo systems, statistics
Day 5	Role of biologics; Exam

Individual Home Assignments

After the week of on-site training, students will receive an individual 38 hours home assignment consisting of written questions and a case study. These individual assignments are to be completed through a frequent exchange with the safescimet teachers using distance learning approach. Written individual assignments are to be completed and submitted via Moodle within 6 weeks after the on-site training and will then be approved by the course leader.

Course Credits

Participants attending the on-site training week only, without completing the exam and/or the home assignment, will be given a certificate of attendance confirming completion of a Continuing Professional Development (CPD) course.
In order to receive the full 3 ECTS credits for a successfully completed course, participants need to pass the written exam of the on-site training week as well as to have successfully completed the home assignment.

Syllabus

The syllabus contains lecture hand outs, list of abbreviations and list of reading materials and will be provided by the course leaders 14 days prior to the course. The information and the material for the individual home assignment will be provided during the first week of the course.

Assessment

The assessment is based on a 2-hour written examination (30 minutes/day of the on-site course) and on the evaluation of the home assignment.

Type	- The purpose of the examination is to test that the examinee has aquired a broad knowledge and comprehension of the course subjects during the lectures. - The percentage of items on the test devoted to a particular topic will roughly correspond to the emphasis given on the topic during the course. - Anatomy/Physiology: 50% - Study design: 25% - In vitro methods: 25%
Assessors	Course leaders
Exam aids	All written exam aids are allowed, especially the provided material: lecture hand outs, list of abbreviations and case studies.

Contact Person

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Course Leaders

Prof Dr Ibrahim Chahoud - Institute for Clinical Pharmacology and Toxicology, Charité – Universitätsmedizin Berlin
Prof Dr Ralf Stahlmann - Institute for Clinical Pharmacology and Toxicology, Charité – Universitätsmedizin Berlin
Dr Michele Bouisset-Leonard - Novartis Institutes for Biomedical Research, Translational Science, Preclinical Safety, Basel, Switzerland

Practical Information

Course credits	3 ECTS credits
Level	Master's level (second cycle higher education)
Location	Hotel Mercure, Invalidenstr. 38, 10115 Berlin, Germany
Teaching methods	Lectures, case reports, demonstrations and home assignments.
Student workload	- Preparation: 12 hours - Course: 38 hours - Assignment: 38 hours - Examination: 2 hours - Total: 90 hours
Course fee	Please visit on www.safescimet.eu **Fees** and **How to apply** for more information.
Course capacity	20 participants
Language	- The official language of the course is English. - No simultaneous translations will be provided.
Course notes	Complete course notes, except for the textbook, will be available for all the participants.
Course accreditation	- safescimet courses meet the criteria for Continuous Professional Development (CPD) diplomas, and are part of Master programme Advanced Safety for Medicines. - When registering for one or several "Stand Alone"courses of our programme, this course provides CPD credits for your individual CPD portfolio. Each course is credited with 38 contact hours. - The course setup is already consistent with the requirements of the Bologna process. Tha full Master programme is undergoing evaluation for being accredited and certified as a regular postgraduate MSc degree at the University of Constance/Germany.

Accommodation

We recommend booking a room in advance under www.mercure.com/de/hotel-5341-mercurehotel-berlin-city/index.shtml for your stay in Berlin at the Hotel Mercure, Invalidenstr. 38, 10115 Berlin. We have a reserved room contingent for 119 € per night, please mention the booking code **Charité**. Please note that these rooms may be booked via phone +49 (0)30 308260 or e-mail h5341@accor.com only. Otherwise, individual hotel booking can be arranged via www.berlin.de/tourismus .

Transport

The course takes place at the Hotel Mercure. The closest underground station **Naturkundemuseum** is less than 100m away. Berlin Tegel Airport is just a 20 minute drive away by Airport Shuttle Bus **TXL Flughafen Tegel** (JetExpressBus) to Washingtonplatz/Hauptbahnhof.

Registration

To apply please visit www.safescimet.eu. Your application needs your registration on www.safescimet.eu.

Cancellation

For our cancellation policy please visit **How to Apply/Terms and Conditions** on www.safescimet.eu.