safescimet course 3.3 - Cellular Toxicology and Predictive Toxicology

Key Questions Addressed

- Cellular physiology and cytotoxic responses
- Adverse Autcome Pathway (AOPs) paradigm
- Intra- and intercellular signalling and mechanisms of cell injury
- Translation of cell injury to in vivo models and the clinic
- Molecular mechanisms of adverse drug reactions and drug development in practice
- Molecular mechanisms of idiosynchratic drug reactions: from bench-to-bed and back
- Stem cell technology and mechanism-based pre-clinical drug safety evaluation
- Quantitative high content imaging of drug-induced cellular perturbation for adverse outcome prediction

Feedback from the Previous Course

"I liked the small cases from industry a lot."

"It was really nice to see people from industry and academia interacting with each other."

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safescimet is currently supported by Hoffmann-La Roche & Sanofi & Bayer Healthcare AG & Department Human and Environmental Toxicology at the University of Konstanz

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 fulfill 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 Cellular Toxicology and Predictive Toxicology and the other single courses of the safescimet programme provide new opportuni-ties for Continuous Professional Development (CPD) purposes 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

In drug development the non-specific interactions of drugs substances or their metabolites pose problems on the cellular level. Therefore there is a need of experts in pre-clinical safety who interpret and understand pre-clinical and clinical data, especially in terms of evaluating the toxicological profile of a candidate drug. It is important for safety scientist to have a broad overview and the ability to understand the connections between molecular events at the cellular level upon chemical exposure and the consequences for organ functioning. The course will provide participants with a comprehensive overview how cells deal with chemical stress at the molecular and cellular level and make them familiar with the fundamentals necessary to understand cellular mechanisms of adverse drug reactions. Special emphasis is put on the recognition that during drug development the involvement of specialist scientist is often required to achieve a multidisciplinary solution. Participant will receive knowledge about the major processes in cytotoxity, become aware of technologies (use of stem cells, bioimaging, in silico modelling) to evaluate cellular stress responses and cytotoxic reactions and will be able to extrapolate the knowledge from the cellular level to the organ and human level.

Key Subjects Covered by the Course

- Consequences of cell injury and biochemical mechanisms
- Adverse Autcome Pathway (AOPs) paradigm
- Cellular defence mechanisms against cell stress
- Molecular mechanisms of cellular senescence, autophagy or cell death
- Intra- and intercellular signalling and mechanisms of cell injury
- Translation of cell injury to in vivo models and the clinic
- Molecular mechanisms of idiosyncratic drug toxicities and ADR
- Stem cell technology and applications in understanding mechanisms of toxicity
- Functional genomic technologies
- Quantitative high content imaging of drug-induced cellular perturbation for adverse outcome prediction

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 course, participants will have acquired an understanding of the relevance of stem cells and other novel therapeutics for drug safety research. More specifically, participants will be able to

- have an appreciation of basic cell biological responses to injury

- know and understand the themes and major processes in cytotoxicity
- to relate the basics of molecular toxicity to the cellular stress response
- learn about new technologies available for cytotoxicity evaluation
- extrapolate the knowledge from cell level to organ and system (human) levels
- integrate the role of in vitro cytotoxicity evaluation in the context of risk assessment

Course Programme

The first week of the course 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	General introduction and molecular mechanisms of ADR; Adverse Outcome Pathway (AOPs) paradigm
Day 2	Consequences of cell injury and biochemical mechanisms; Molecular mechanisms of cell death
Day 3	Intracellular signalling after cell injury; Quantitative high content imaging of drug-induced cellular perturbations
Day 4	Intercellular communication; Idiosyncratic drug toxicities
Day 5	Case studies

Individual Home Assignments

After the week of on-site training, students receive an individual 38 hours home assignment consisting of written questions and a case study. These individual assignments will 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

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.

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.

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 on the last day of the first course week 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. - Case studies - Experimental Design: 5% - Pre-clinical: 55% - Clinical: 25%T - Translational: 15%
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

Professor Bob van de Water - Division of Toxicology, Leiden Academic Centre for Drug Research, Leiden University, Leiden, The Netherlands
Dr. Eckhard von Keutz - Bayer HealthCare, Wuppertal, Germany

Practical Information

Course credits	3 ECTS credits
Level	Master's level (second cycle higher education)
Location	Human and Environmental Toxicology, University of Konstanz.
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 Konstanz/Germany.

Accommodation

There are various accommodation options within 10–20 minutes walking distance to the venue. Three hotels located in the direct vicinity of the conference venue are 'De Doelen', 'Mayflower', and 'Nieuw Minerva'. Reservations can be arranged individually via www.hotelsvanleiden.nl.

Transport

The course takes place at the Leiden University, 1.5 km from the central train station and approximately 15 minutes by train from Amsterdam Schiphol Airport. To see how to get there, please visit www.leidenuniv.nl/loc/index.html.

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.