safescimet course 3.5 - Mutagenesis and Carcinogenesis

Key Questions Addressed

- Overview on the biology of carcinogenesis
- Principles of mutagenesis and carcinogenesis
- Examples of the mutagenic/carcinogenic actions at the cellular, biochemical and molecular level
- Experimental design for specific identification of mutagenic/carcinogenic compounds
- Interpretation of dose-response curves
- Extrapolation of animal findings and experimental data to human
- Safety data reports, authority guidelines
- Risk-benefit evaluation

Feedback from the Previous Course

"Very interesting to meet people from different working places."
"I liked the real life industry-supplied case studies very much."

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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 Mutagenesis and Carcinogenesis 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

Besides heredity and environmental factors, chemical exposure is responsible for approximately two thirds to three quarters of all cancers. The development of new chemical compounds holds the potential risk of harmful mutagenic and/or carcinogenic effects to humans. Minimising these risks during drug development requires appropriate experimentation and expert knowledge whose basic principles will be delivered with this course. Special emphasis will be given to the biology of cancer formation, the identification of mutagens and carcinogens and their modes of action on the cellular, biochemical and molecular level. In silico methods prediction as well as animal test systems and tissue culture assays for carcinogenicity testing will be presented. Furthermore, the importance of responsibly estimating dose-dependent probabilities of mutagenic/carcinogenic effects (risk assessment) and the risk-benefit evaluation will be discussed. In case studies, participants will review and assess safety data for mutagenic and carcinogenic compounds.

Key Subjects Covered by the Course

- Overview on the biology of carcinogenesis
- Principles of mutagenesis and carcinogenesis
- Examples of the mutagenic/carcinogenic actions at the cellular, biochemical and molecular level
- Experimental design for specific identification of mutagenic/carcinogenic compounds
- Interpretation of dose-response curves
- Extrapolation of animal findings and experimental data to human
- Safety data reports, authority guidelines
- Risk-benefit evaluation

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 understand basic principles in chemical mutagenesis and carinogenesis in a broader context, and will perform risk assessment and risk-benefit evaluations for mutagenic and/or carcinogenic compounds at an advanced level. More specifically, participants will be able to

- understand key cellular and molecular alterations in carcinogenesis
- identify and characterise mutagenic effects of chemical compounds
- elucidate mechanisms of mutagenic and carcinogenic action at the cellular, biochemical and molecular level
- review and assess safety data generated for a mutagenic/carcinogenic compound
- estimate the probability of occurrence of mutagenic and/or carcinogenic effects (risk assessment)

- contribute responsible to risk-benefit evaluation

Course Programme

The first week of the course in Amsterdam 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	Cancer: Role in public health, epidemiology and etiology; Carcinogenesis overview
Day 2	In silico toxicology; Genotoxicity
Day 3:	Tumor biology, carcinogenesis
Day 4	Non-genotoxic carcinogenesis; Cytotoxic agents; Risk assessment
Daily	Daily exams of 30-45 minutes

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 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. - Experimental Design: 15% - Pre-clinical: 65% - Clinical: 5% - 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

Prof Dr Bettina Grasl-Kraupp - Institute for Cancer Research, Medical University Vienna, Vienna
Dr Hans-Jörg Martus - Novartis Institutes for BioMedical Research, Basel, Switzerland

Practical Information

Course credits	3 ECTS credits
Level	Master's level (second cycle higher education)
Location	University of Konstanz, Universitätsstrasse 10, 78457 Konstanz, 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 generally room our participants in the Hotel Hirschen (www.hirschenkonstanz.de/html/eng/). Please contact the safescimet Office (safescimet@uni-konstanz.de) for information on special booking codes.

Transport

Konstanz can be reached in approximately 1 hour by train from Zürich Airport, Switzerland or in 2.5 hours from Stuttgart Airport, Germany.
More details, also for parking in case you are coming by car, will follow in the Welcome letter for registered participants.

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.