



## Mutagenesis and Carcinogenesis

Key issues to be covered by the course:

- ⌚ Biology of cancer formation
- ⌚ Identification of mutagens/carcinogens
- ⌚ Elucidation of mode of action of mutagenic/carcinogenic compounds
- ⌚ Risk assessment of mutagens/carcinogens
- ⌚ Risk-benefit evaluation

### Course 4.5. Mutagenesis and Carcinogenesis

*28. November – 2. December 2011  
Centre of Pharmacy  
University of Vienna*

*5. – 9. December 2011  
Home assignment*

## Introduction

SafeSciMET is a new and unique pan-European network of academia and pharmaceutical industry offering a comprehensive modular education and training programme in Safety Sciences. The programme is covering all aspects of safety in drug development to ensure that European Drug Safety Scientists in the pharmaceutical industry, regulatory authorities, and academia are at the forefront of their field.

The course **Mutagenesis and Carcinogenesis** is part of this new continuing education programme for Safety Sciences professionals and is one of the mandatory courses of the Safety Sciences programme. Successful attendance is required for the new European Masters degree of Advanced Safety Sciences for Medicines designed by SafeSciMET.

## Why join the course

Aim and mission of Safety Sciences is the identification of potential harmful effects of chemical compounds to humans to ensure risk prevention. Appropriate experimentation and expert judgement allow to minimise the probability of the occurrence of adverse effects of chemicals, which in the past have sometimes been of catastrophic dimension. Comprehensive education and training in Safety Sciences is mandatory to fulfill these tasks. This course offers an education and training programme in the field of mutagenesis and carcinogenesis on an up-to-date level.

### Course Objectives

This course will provide participants with a comprehensive overview of principles in mutagenesis and carcinogenesis. This knowledge will help successful attendees to identify and to characterise mutagenic and/or carcinogenic action of chemical compounds. They also will achieve skills allowing to interpret safety data for risk assessment and to perform risk-benefit evaluations.

### Key areas covered by this course

- **Overview on the biology of carcinogenesis**
- **Basic principles in mutagenesis and carcinogenesis**
- **Prototypical examples of the action of chemical mutagens/ carcinogens at the cellular, biochemical, and molecular level**
- **Design of proper experimental setups to specifically identify mutagenic/carcinogenic compounds**
- **Interpretation of dose-response curves**
- **Extrapolation from experimental data to humans**
- **Training to review and to assess safety data generated for prototypical mutagenic/carcinogenic compounds**
- **Estimation of the probability of occurrence of mutagenic and/or carcinogenic effects (risk assessment)**
- **Risk-benefit evaluation**

## Target Group

SafeSciMET students, academics, and representatives of the pharmaceutical industry and regulatory authorities, who need broad and comprehensive understanding of the drug development process with particular emphasis on safety.

## Learning Outcomes

Successful attendees will understand basic principles in chemical mutagenesis and carcinogenesis in a broader context, which will assist in communicating with experts in other fields and to perform risk assessment and risk-benefit evaluations for mutagenic and/or carcinogenic compounds at an advanced level. More specifically, attendees will be trained to

- understand key cellular and molecular alterations in carcinogenesis
- identify and characterise mutagenic and carcinogenic 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 and/or carcinogenic compound
- estimate the probability of occurrence of mutagenic and/or carcinogenic effects (risk assessment)
- contribute responsibly to risk-benefit evaluation



# Course Programme

## The Syllabus

A syllabus containing an introductory chapter, lecture handouts, list of abbreviations, definitions and reading material will be provided by the course leader 14 days prior to the course.

## Assessment

The assessment is based on a 2-hours written examination on the last day of the course and on the evaluation of the home assignment. The material for the home assignment will be handed out during the first week of the course

<b>Type</b>	Knowledge and comprehension in the field of mutagenesis and carcinogenesis will be examined. The percentage of questions devoted to a particular topic will roughly correspond to the emphasis given to this topic in the course: Experimental design: 15% Translational: 15% Pre-clinical: 65% Clinical: 5%
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<b>Assessors(s)</b>	Course directors
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<b>Exam aids</b>	All written exam aids are allowed.
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<b>Course administrator:</b>	Prof. Dr. Bettina Grasl-Kraupp Institute for Cancer Research Medical University Vienna Borschkegasse 8a A-1090 Vienna/Austria  Email: <a href="mailto:bettina.grasl-kraupp@meduniwien.ac.at">bettina.grasl-kraupp@meduniwien.ac.at</a> Phone: +43-1-4277-65137
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# Practical Information

<b>Course Credits:</b>	3 ECTS credits
<b>Level:</b>	Master's level (second cycle higher education)
<b>Course Dates:</b>	28. November – 2. December 2011
<b>Location:</b>	University Vienna Centre of Pharmacy Althanstraße 14 A-1090 Vienna Course room 2F363.2
<b>Teaching methods:</b>	Lectures, case workgroup discussions, presentations and discussions. The course is largely based on the use of cases.
<b>Student Workload:</b>	Preparation: 12 hours Course: 38 hours Examination: 2 hours Home assignment: 38 hours Total: 90 hours
<b>Course Fee:</b>	EUR 2.500 – EUR 750 (dependant on category of student) (please visit <a href="http://www.SafeSciMET.eu">www.SafeSciMET.eu</a> . <b>How to apply for more information</b> )
<b>Application deadline:</b>	<b>October 28<sup>th</sup>, 2011</b>
<b>Course Capacity:</b>	25 participants
<b>Language:</b>	The course will be held in English. No simultaneous translation will be provided.
<b>Course notes:</b>	Course material, including literature, will be available for all participants. Textbook recommendation: 'Casarett and Doull's Toxicology. The Basic Science of Poisons' Curtis D. Klaassen, Ed, The McGraw-Hill Companies, 2007.
<b>Course accreditation:</b>	The course meets the criteria for Continuous Professional Development (CPD) diplomas and will be part of a (forthcoming) European Masters degree of Advanced Safety Sciences for Medicines. When registering for a "stand alone" course only, this course provides CPD credits for the individual CPD portfolio.  For more information see <a href="http://www.SafeSciMET.eu">http://www.SafeSciMET.eu</a>

## COURSE LEADERS

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## LECTURERS

Alexander Amberg, Sanofi-Aventis, GER  
Walter Berger, Medical University Vienna, AU  
Wilfried Bursch, Medical University Vienna, AU  
Wolfgang Dekant, University of Würzburg, GER  
Barbara Dietrich, Baxter, Vienna, AU  
Albert Duschl, University of Salzburg, AU  
Roland Froetschl, BfARM, GER  
Bettina Grasl-Kraupp, Medical University Vienna, AU  
Melanie Guerard, Roche, CH  
Wolfgang Huber, Medical University Vienna, AU  
Anthony Lynch, GSK, UK  
Hans-Jörg Martus, Vovartis, CH  
Jonathan Moggs, Novartis, CH  
Martin Paparella, UBA Vienna, AU  
Veronique Thybaud, Sanofi-Aventis, F  
Klaus Weber, Harlan/RCC, CH

## REGISTRATION

Please visit [www.safescimet.eu](http://www.safescimet.eu) to register. On the homepage, please go to **How to Apply** and sign up:

[For MSc of Advanced Safety Courses](#)

[For Continuing Professional Development \(CPD\)](#)

[For single courses](#)

You will be notified that your registration has been received.

**The closing date to register for this course is October 28<sup>th</sup>, 2011.**

Please note that the number of participants is limited to 25. It is highly advisable to send in your registration form as soon as possible. Registration will be made on a **first come, first served** basis.

## ACCOMMODATION

The Hotel is located close to the course venue (5 minutes walking distance).

Hotel Arkadenhof

Viriotgasse 5

A-1090 Vienna

Phone: +43-1-310-08-37

[www.arkadenhof.com](http://www.arkadenhof.com)

Further hotels: [www.booking.com/city/at/vienna.en.html](http://www.booking.com/city/at/vienna.en.html)



## CANCELLATION

Cancellation of a pre-registered student is possible, upon written notice by October 25<sup>th</sup>, 2011. Before that date the course fee will be refunded except for an administrative fee of EUR 75. After that date, no refunds can be made for cancellations.