

# safescimet course 2.2 - Regulatory Requirements and Guidelines

## Key Questions Addressed

- Drug development process and regulatory requirements
- EU & ICH guidelines and the Common Technical Document
- ICH guideline on nonclinical safety
- Extrapolation of animal data, human translation and risk assessment
- Species selection for nonclinical studies and 3Rs principles
- Reproductive toxicity testing, pregnancy labeling
- Testing genotoxic and carcinogenic potential
- First in Human studies and regulatory guidelines for safe dose estimation
- Nonclinical safety testing of biologics
- Environmental risk of pharmaceuticals

## Feedback from the Previous Course

"Excellent way to work with so many case studies."

"It was nice to be able to discuss with the teachers between the lectures."

## 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 Regulatory Requirements and Guidelines 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](http://www.safescimet.eu) for details of the full course programme and confirmation of course dates.

## Course Objectives

Drug development and production underlies laws and regulations to secure protection of human, test animals and the environment. Guidelines provide advice to applicants on specific scientific issues reflecting a harmonized EU approach to fulfil the pharmaceutical legislation. This course will provide participants with a comprehensive overview of the required in vitro and in vivo nonclinical studies, strategies for the development and risk assessment of new pharmaceuticals. While the focus of this course is mainly on the EU perspective, the ICH procedures and guidelines reflecting the international harmonization of requirements (in the EU, US and Japanese) are also covered. Special emphasis is put on the translational science methodologies for the transfer into humans of nonclinical data generated from integrated in vitro and animal models. The study needs for specific patient populations (pregnant women, paediatric, geriatric) are also part of this course's curriculum. At course completion students will have knowledge of the type and rationale of the tests required and will be able to determine which data need to be generated in each situation and for which stage of the development.

## Key Subjects Covered by the Course

- Drug development process and regulatory requirements
- EU & ICH guidelines and the Common Technical Document
- ICH guideline on nonclinical safety
- Extrapolation of animal data, human translation and risk assessment
- Species selection for nonclinical studies and 3Rs principles
- Reproductive toxicity testing, pregnancy labeling
- Testing genotoxic and carcinogenic potential
- First in Human studies and regulatory guidelines for safe dose estimation
- Nonclinical safety testing of biologics
- Environmental risk of pharmaceuticals

## 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 in Lisbon 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 should have an integrated view on the regulatory requirements and guidelines relevant for the development and marketing of new pharmaceuticals. They will understand the type and rationale of the tests required and will identify which data is necessary in each stage of development. More specifically, participants will be able to

- understand the concept of "relevant species" and recognize the value of its use for human extrapolation of nonclinical study outcomes

- plan the nonclinical safety programs for different types of pharmaceuticals and understand the translational aspects of medicines development
- know and understand the European and international nonclinical regulatory guidelines and the situations where they will apply or deviate
- adapt the standard protocols into specific situations, e.g. pathologies, patient populations
- use and integrate the information from multiple sources/ studies as a weight of evidence approach for human risk assessment

## Course Programme

The first week of the course in Lisbon 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	Overview about the regulatory systems in the EU and harmonization issues
Day 2	ADME PK/PD / extrapolation from animal data to human
Day 3	Risk assessments on immunotoxicity and carcinogenicity / biopharmaceuticals safety assessment
Day 4	Reproductive toxicity testing / first in human guidelines / nonclinical safety of pediatric drugs
Day 5	Exploratory clinical trials / patient populations

## 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

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	<ul style="list-style-type: none"> <li>- The purpose of the examination is to test that the examinee has acquired a broad knowledge and comprehension of the course subjects during the lectures.</li> <li>- 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.</li> <li>- Experimental Design: 25%</li> <li>- Pre-clinical/Manufacturing: 50%</li> <li>- Clinical: 5%</li> <li>- Translational: 20%</li> </ul>
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

### Professor Beatriz Silva Lima

Faculdade de Farmacia, Universidade de Lisboa Avenida das Forças Armadas 1600 Lisboa, Portugal

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## Course Leaders

**Professor Beatriz Silva Lima** - Faculty of Pharmacy, Universidade de Lisboa, Avenida Professor Gama Pinto, 1649-003 Lisboa, Portugal

**Director Per Spindler** - Biopeople, Faculty of Health and Medical Sciences, University of Copenhagen, Universitetsparken 2, DK-2100 Copenhagen, Denmark

**Dr Kirstin Meyer** - Bayer Pharma AG, Berlin, Germany

## Practical Information

Course credits	3 ECTS credits
Level	Master's level (second cycle higher education)
Location	Faculty of Pharmacy, Universidade de Lisboa, Portugal
Teaching methods	Lectures, case reports, demonstrations and home assignments.
Student workload	<ul style="list-style-type: none"> <li>- Preparation: 12 hours</li> <li>- Course: 38 hours</li> <li>- Assignment: 38 hours</li> <li>- Examination: 2 hours</li> <li>- Total: 90 hours</li> </ul>
Course fee	Please visit on <a href="http://www.safescimet.eu">www.safescimet.eu</a> <b>Fees</b> and <b>How to apply</b> for more information.
Course capacity	20 participants
Language	<ul style="list-style-type: none"> <li>- The official language of the course is English.</li> <li>- No simultaneous translations will be provided.</li> </ul>
Course notes	Complete course notes, except for the textbook, will be available for all the participants.
Course accreditation	<ul style="list-style-type: none"> <li>- safescimet courses meet the criteria for Continuous Professional Development (CPD) diplomas, and are part of Master programme Advanced Safety for Medicines.</li> <li>- 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.</li> <li>- The course setup is already consistent with the requirements of the Bologna process. The full Master programme is undergoing evaluation for being accredited and certified as a regular postgraduate MSc degree at the University of Konstanz/Germany.</li> </ul>

## Accommodation

We recommend reserving a room for your stay in Lisbon at the Lisboa [Sana Metropolitan Hotel Rua Soeiro Pereira Gomes](#), Parcela 2, Entrecampos, 1600-198 Lisbon.

## Transport

The course takes place at the Lisbon University, 10 minutes by taxi from Airport and 5 minutes walking distance from Lisbon Sana Hotel.

## Registration

To apply please visit [www.safescimet.eu](http://www.safescimet.eu). Your application needs your registration on [www.safescimet.eu](http://www.safescimet.eu).

## Cancellation

For our cancellation policy please visit **How to Apply/Terms and Conditions** on [www.safescimet.eu](http://www.safescimet.eu).