safescimet

European Modular Education and Training Programme in Safety Science for Medicines

Universität Konstanz

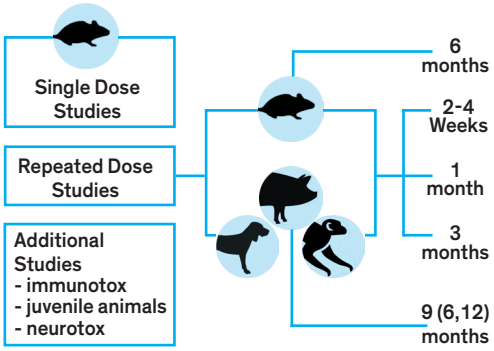
efpia

safescimet course 2.2 - Regulatory Requirements and and Guidelines

(27–31 January 2020, Lisbon, Portugal)

A unique opportunity to broaden your knowledge of drug discovery and development with special emphasis on drug safety.

safescimet offers an outstanding faculty of academic and industry experts and an interactive programme, including case studies from the pharmaceutical industry provding a broad understanding of the latest developments in safety sciences.



Genotoxicity	Carcinogenicity	Reproduction Toxicology
- in vitro - in vivo	1 life-span + 1 additional model	- fertility - embryofetal toxicity - peri-post natal toxicity

Regulatory Requirements and Guidelines

This course will provide participants with a comprehensive overview of the required in vitro and in vivo nonclinical studies, development strategies as well as risk assessment for new pharmaceuticals (small molecules and biologics). While the focus of this course is on the EU perspective, the ICH procedures and guidelines reflecting the international harmonization of requirements (in the EU, US and Japan) are also covered. Special emphasis is put on translational science methodologies of nonclinical data to humans based on an integrated safety assessment. Studies needed for specific patient populations (pregnant women, pediatric, 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

- 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 assessment of pharmaceuticals extrapolation

Learning Outcomes

- 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

Link to apply to this course

Deadline for registration 07 January 2018

Course Organisers

Prof Beatriz da Silva Lima
Faculty of Pharmacy, Universidade de Lisboa

Director Per Spindler
Biopeople, Faculty of Health and Medical Sciences, University of Copenhagen

Dr Kirstin Meyer
Bayer Pharma AG, Germany

Participant Feedback

Excellent way to work with so many case studies.

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

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