safescimet

European Modular Education and Training Programme in Safety Science for Medicines

Universität Konstanz

efpia

safescimet course 5.1 - Clinical safety: Pre-Approval Drug Development

(11–14 February 2019, Basel, Switzerland)

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.

Pathology Interpretation in Drug Development

The aim of this course is to introduce the principles of translational safety as a tool to bridge preclinical and clinical safety assessments as well as safety management throughout the clinical phase of drug development up to submission for market authorization. Lecturers and students will discuss the strengths and limits of these approaches and will have insight into the overall strategy of clinical safety evaluation prior to drug approval. Case studies from the development of successful new drugs as well as from discontinued compounds are used to illustrate the process of developing safe medicines. Also regulatory requirements from the major markets are presented and discussed. Upon completion of the course the students will have an overall understanding of integrated drug safety activities, how to approach safety margins during translation from animal to man and the benefit / risk assessment methodology used during drug development.

Key Subjects

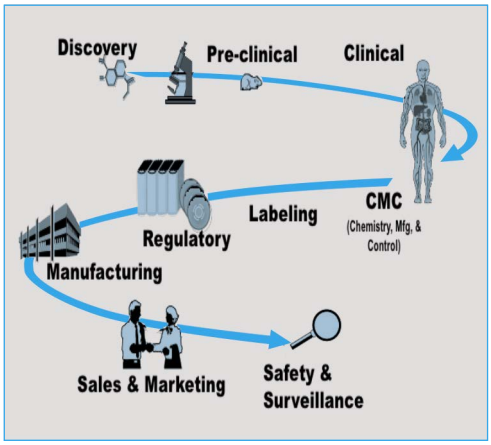
- Integrated and translational drug safety, signal detection and biomarkers
- Integrated safety management planning and clinical safety with organ focus on main target toxicities: liver, kidney, cardiovascular system, immune system, neurotoxicity
- Clinical trials methodology and safety issues, risk benefit assessment, stratification and management
- Population selection, epidemiological and statistical aspects
- Risk evaluation, mitigation strategies

Learning Outcomes

- Understand integrated drug development in parallel to integrated drug safety evaluation
- Know and understand translational organ toxicity from animal to man
- Appreciate the safety concern in the context with the benefit
- Know and understand the prediction and detection of adverse events during clinical drug development
- Know and understand risk assessment methodology
- Apply a risk evaluation and mitigation strategy

Link to apply to this course

Deadline for registration 05 February 2019



Course Organisers

Prof Dr Daniel Dietrich
Human and Environmental Toxicology, Faculty of Biology, University of Konstanz, Germany

Dr Lucette Doessegger
Pharma Consultant
Switzerland

Participant Feedback

Professional faculty and interested audience. Good learning atmosphere.

Interaction with course members was good and easy. Plenty of opportunities for networking.

Really engaged presenter, good discussions after the lectures.

The content of the lectures and the quality of the speakers was great. I enjoyed the interaction with the other participants and the course leaders. The facilities were exceptional.

Good mix between lectures and case studies.

safescimet Executive Office
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To contact us or to register to our courses visit safescimet@uni-konstanz.de or http://ssm.afww.uni-konstanz.de/safescimetcourses

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