safescimet course 5.2 - Clinical Safety: Post-Approval

Key Questions Addressed

- Worldwide regulatory requirements and organization for products safety
- Modalities of detection, analysis and validation of safety signals (pharmacovigilance) and risk assessment.
- Pharmacoepidemiology as a tool for the identification and study of drug-induced adverse events and pharmaceutical risk assessment
- Risk minimization activities in the post-marketing phase, incl. labelling, medication errors and misuse, and the measure of their effectiveness
- Post-approval safety commitments
- Quality insurance, inspection and audits
- Safety issues and crises

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."

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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 Clinical Safety: Post-Approval 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

Drug safety in human patients is the ultimate goal of drug safety scientists. Because limitations of patient populations studied during drug development and uncertainties related to potential drug-drug interactions or rare or idiosyncratic adverse reactions, it is important to pay careful attention to human safety to achieve a better understanding of the safety of drugs on the market used in a wider patient population, for long treatment duration and on various co-medication compared to the population included in the approval package. This course will provide participants with an overview of the current knowledge on the clinical assessment and follow-up of drug safety post-approval and human safety. It will also include pharmacovigilance activities, risk management and risk benefit analysis.

Key Subjects Covered by the Course

- Worldwide regulatory requirements and organization for products safety
- Modalities of detection, analysis and validation of safety signals (pharmacovigilance) and risk assessment.
- Pharmacoepidemiology as a tool for the identification and study of drug-induced adverse events and pharmaceutical risk assessment
- Risk minimization activities in the post-marketing phase, incl. labelling, medication errors and misuse, and the measure of their effectiveness
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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 consists of four 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 aspects of adverse drug reactions and risk minimization activities in the post-marketing phase. More specifically, participants will be able to

- appreciate the need to detect drug-induced adverse effects in relation to recommended thera peutic use, misuse or abuse
- know and understand the different kinds of modalities applicable to the detection, analysis and validation of safety signals and drug-induced adverse events
- know study types in pharmaco-epidemiology and designs as a tool for risk assessment and drug safety
- know and understand risk minimization activities post-approval and the measure of their effectiveness
- know the major regulatory issues in post-approval clinical drug safety
- know the quality processes and regulatory inspection and audits in clinical drug safety

Course Programme

The first week of the course consists of four 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	Pharmacovigilance organization, regulatory aspects and medical aspects of averse drug reactions
Day 2	Pharmacovigilance, signal detection, evaluation & PV master files
Day 3	Post-marketing risk assessment including post-marketing studies and risk minimization
Day 4	Effectiveness of risk minimization activities and risk management

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: 0% - Pre-clinical / Manufacturing: 0% - Clinical: 90% - Translational: 10%
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 Marc Pallardy - Faculté de Pharmacie, Université Paris-Sud, France
Dr Henri Caplain
Dr Armelle Biola-Vidamment - Faculté de Pharmacie, Université Paris-Sud, France

Practical Information

Course credits	3 ECTS credits
Level	Master's level (second cycle higher education)
Location	Faculté de Pharmacie, Université Paris-Sud, France
Teaching methods	Lectures, case reports, demonstrations and home assignments.
Student workload	- Preparation: 12 hours - Course: 23 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 23 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

For those who want to be close to the Faculty, please contact Prof Dr Marc Pallardy, to have a list of convenient hotels. If you want to stay in central Paris, we recommand that you book an hotel close to the RER B line.

Transport

The lecture location is at Faculté de Pharmacie, Université Paris-Sud, 5 rue Jean- Baptiste Clément, 92290 Châtenay-Malabry (www.pharmacie.u-psud.fr/fr/index.html); lectures will be in the **EH27** room. The Faculty of Pharmacy is in the south of Paris and is close to the *RER B station *"Croix de Berny". Transportation from "Croix de Berny" to the Faculty will be organised in the morning for the students; at the end of the day, students will also be conducted back to the "Croix de Berny" RER station. To see how to get to RER B "Croix de Berny" station please visit http://www.ratp.fr.

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.