safescimet

European Modular Education and Training Programme in Safety Science for Medicines

Universität Konstanz

efpia

safescimet course 5.2 - Clinical safety: Post-Approval

(20–23 January 2020, Paris, France)

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.

Clinical safety: Post-Approval

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

- 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

Learning Outcomes

- 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

Link to apply to this course

Deadline for registration 10 January 2020

Course Organisers

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Dr Henri Caplain
Expert in pharmaceutical risk management

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Participant Feedback

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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