DIA/MEB Excellence in Pharmacovigilance

Module 3: Risk Management

Virtual Live Training Course

16 November 2022
08:30-18:00 CET

COURSE DIRECTORS

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FACULTY

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OVERVIEW

Module 3 corresponds to GVP Modules V, VIII, XV and XVI.
In accordance with the GVP Module V on Risk Management System, Risk Management Plans (RMPs) should be submitted by companies to propose activities aiming to identify, characterise or minimise risks associated with medicinal products. Given the potential public health implications and costs of such interventions, RMPs should be based on robust data. Specific examples of data collection and analysis will be presented in this session.
Besides, pharmaco-epidemiological studies, which are the fundamentals of "additional" Pharmacovigilance activities, are discussed. This session also presents recent developments regarding risk communication.

TARGET AUDIENCE

Professionals with experience in safety related activities of the drug development process and/or those with a need of a holistic overview about all PV related regulatory requirements will benefit most, such as:

- Pharmacovigilance Officers, Managers, Specialists, Experts, or Coordinators
- Regulatory Compliance, Quality or Safety departments Heads, Directors or Managers

Level: /Intermediate

08:30 **Risk Management Plans – Regulatory Perspective: GVP Module V Revision 2**
Paul ten Berg

09:30 **Risk Management Plans – Industry Perspective**
Jan Petracek

10:30 COFFEE BREAK

11:00 **Harmonisation of RMP (HaRP) in Europe**
Paul ten Berg

11:30 LUNCH BREAK

12:30 **Epidemiological Methods and Pharmacovigilance**
Fakhredin Sayed Tabatabaei

14:00 **Effectiveness of Risk Minimisation Measures – Regulatory Perspective**
Anita Volkers

15:00 COFFEE BREAK

15:30 **Effectiveness of Risk Minimisation Measures – Industry Perspective**
Jan Petracek

16:30 **Risk Communication in EU – Challenges and Possibilities**
Jan Petracek

17:30 **Discussion and Q&A**

18:00 **END OF MODULE 3**

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