DIA/MEB Excellence in Pharmacovigilance

Module 2: Regulatory Aspects in Pharmacovigilance

Virtual Live Training Course

15 November 2022
08:30-18:15 CET

COURSE DIRECTORS

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OVERVIEW

Module 2 covers GVP Modules I to IV and will provide the safety reporting requirements with case studies, as well as safety data classification, using MedDRA terminology and safety data retrieval using Standardised MedDRA Queries (SMQs).
It covers establishment of a Quality Management System in Pharmacovigilance and includes aspects of the applicable GVP modules, as well as preparation and conduct of audits and inspections.

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 **SUSAR Reporting in Clinical Trials and Case Studies**
Wendy Huisman

10:45 COFFEE BREAK

11:15 **MedDRA and Standardised MedDRA Queries**
Evelyn Olthof

12:15 **Pharmacovigilance System Master File**
Wendy Huisman

12:45 LUNCH BREAK

13:45 **The Role of the Qualified Person Responsible for PV**
Wendy Huisman

14:15 **Audits and Inspections in Pharmacovigilance – Regulatory Perspective**
Marian Verbruggen

15:15 COFFEE BREAK

15:45 **Quality Management System**
Stephanie Martin

17:45 **Discussion and Q&A**

18:15 **END OF MODULE 2**

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