Regulatory Aspects in Pharmacovigilance and Practical Examples

14-15 May 2019
Park Plaza Amsterdam Airport Hotel, Netherlands

OVERVIEW

This Module is part of the MEB/DIA Excellence in Pharmacovigilance training course

The roles and responsibilities of marketing authorisation holders and national Competent Authorities in the conduct of Pharmacovigilance are defined in EU legislation and further detailed in the Good Pharmacovigilance Practices (GVP). Module 2 will provide the safety reporting requirements with case studies, the roles and responsibilities of all stakeholders of clinical trials in line with the implementing texts published in relation to Directive 2001/20/EC and the new Regulation (EU) 536/2014. It will also cover individual and periodic adverse reaction reporting requirements of marketing authorisation holders in the post-authorisation phase and illustrations based on case studies.

This module will also provide an understanding of safety data classification, using MedDRA terminology and safety data retrieval using Standardised MedDRA Queries (SMQs).

Key elements will be provided for the establishment of a quality system in Pharmacovigilance including aspects of the applicable GVP modules, the elaboration of Standard Operating Procedures (SOPs) and the preparation for audits and inspections.

COURSE DIRECTOR

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FACULTY

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DAY 1

REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

08:00 REGISTRATION

08:30

REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

08:30 SUSAR Reporting in Clinical Trials and Case Studies
Gaby Danan

10:00 COFFEE BREAK

10:30 SUSAR Reporting in Clinical Trials and Case Studies continued
Gaby Danan

12:00 LUNCH

13:00 The Role of the Qualified Person Responsible for Pharmacovigilance
Wendy Huisman

13:45 Preparation of Development Safety Update Reports (DSURs)
Wendy Huisman

14:30 COFFEE BREAK

14:45 Preparation of Periodic Safety Update Reports (PSURs)
Wendy Huisman

15:30 Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies
Gaby Danan

17:00 COFFEE BREAK

17:15 Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies continued
Gaby Danan

18:15 END OF DAY 1

DAY 2

08:30 Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies continued
Gaby Danan

10:15 COFFEE BREAK

10:30 Reporting Requirements in Special Situations in the Post-authorisation Phase and Case Studies
Stephany Suoth, MEB

12:00 LUNCH

13:00 MedDRA and Standardised MedDRA Queries (SMQs)
Ineke Crijns, MEB

14:00 Pharmacovigilance System Master File (PSMF)
Healthcare Inspectorate

14:45 COFFEE BREAK

15:00 Audits and Inspections in Pharmacovigilance - Regulatory Perspective
Healthcare Inspectorate

16:00 COFFEE BREAK

16:15 Audits and Inspections in Pharmacovigilance - Industry Perspective
Wendy Huisman

17:15 END OF DAY 2 / MODULE 2