Joint DIA/MEB Excellence in Pharmacovigilance
Virtual Live Training Course
Available as Modules 1-5 I From 8 to 26 November 2021

"Excellence in Pharmacovigilance" Module 1: Post-Marketing

Module 1 will cover individual and periodic adverse reaction reporting requirements of marketing authorisation holders in the post-authorisation phase with illustrations based on case studies as practical examples.

Day 1 8 Nov, 08:30-15:00

08:30 Welcome

09:00 Keynote: PRAC: Present and Future of Pharmacovigilance

Liana Gross-Martirosyan, Alternate PRAC Member, Netherlands

10:00 Break

10:30 Expedited Reporting Requirements in the Post-Authorisation Phase and Case Studies

Wendy Huisman, Director, Vigifit, Netherlands

12:00 Break

12:30 Expedited Reporting Requirements in the Post-Authorisation Phase and Case Studies continued

Wendy Huisman, Director, Vigifit, Netherlands

14:30 Discussion and Q&A

15:00 End of Day 1

Day 2 9 Nov, 09:00-13:00

09:00 Reporting Requirements in Special Situations in the Post-Authorisation Phase

Anja van Haren, EudraVigilance Coordinator, Medicines Evaluation Board, Netherlands

10:00 Clinical Evaluation of Adverse Drug Reactions

Joao Rocha, Professor of Pharmacology, Immunopharmacology and Pharmacotherapy, Faculty of Pharmacy – University of Lisbon, Portugal

11:00 Break

11:30 Preparation of Periodic Safety Update Reports (PSURs)

Helen Morrison, Global Periodic Reports Officer, Global Patient Safety & Pediatrics, Amgen, United Kingdom

12:30 Discussion and Q&A

13:00 End of Module 1

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"Excellence in Pharmacovigilance" Module 2: Safety Aspects in Clinical Trials

Module 2 will provide the safety reporting requirements with case studies, the roles, and responsibilities of all stakeholders in clinical trials in line with the implementing texts published in relation to Directive 2001/20/EC and the new Regulation (EU) 536/2014.

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

Day 1 11 Nov, 08:30-13:00

08:30 Welcome

09:00 SUSAR Reporting in Clinical Trials and Case Studies

Wendy Huisman, Director, Vigifit, Netherlands

10:30 Break

11:00 SUSAR Reporting in Clinical Trials and Case Studies continued

Wendy Huisman, Director, Vigifit, Netherlands

12:30 Discussion and Q&A

13:00 End of Day 1

Day 2 12 Nov, 09:00-13:00

09:00 Preparation of Development Safety Update Reports (DSURs)

Helen Morrison, Global Periodic Reports Officer, Global Patient Safety & Pediatrics, Amgen, United Kingdom

10:00 MedDRA and Standardised MedDRA Queries (SMQs)

Evelyn Olthof, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

11:30 Break

12:00 Clinical Trials Regulation (EU) NO 536/2014 – Safety Reporting and Monitoring. What will change?

Elke Stahl, CTFG Co-Chair, Clinical Trials Department, Federal Institute For Drugs and Medical Devices, Germany

12:30 Discussion and Q&A

13:00 End of Module 2

"Excellence in Pharmacovigilance" Module 3: Quality Management System

Module 3 of the Joint DIA/MEB "Excellence in Pharmacovigilance" covers establishment of a Quality Management System in Pharmacovigilance.

It includes aspects of the applicable GVP modules, as well as preparation and conduct of audits and inspections. This module also addresses risk-based assessments, document management and PV agreements.

Day 1 17 Nov, 08:30-13:00

08:30 Welcome

09:00 Pharmacovigilance System Master File (PSMF)

Aurélia Mazon, Senior Inspector for Pharmacovigilance, Health and Youth Care Inspectorate, Netherlands

10:00 Audits and Inspections in Pharmacovigilance – Regulatory Perspective

Pieter Grotenhuis, Senior Inspector for Pharmacovigilance, Health and Youth Care Inspectorate, Netherlands

11:00 Break

11:30 Audits and Inspections in Pharmacovigilance – Industry Perspective

Wendy Huisman, Director, Vigifit, Netherlands

12:30 Discussion and Q&A

13:00 End of Day 1

Day 2 18 Nov, 09:00-12:30

09:00 "Risk based" Activities, Documentation and Pharmacovigilance Agreements

Wendy Huisman, Director, Vigifit, Netherlands

10:30 Break

11:00 The Role of the Qualified Person Responsible for PV (QPPV)

Wendy Huisman, Director, Vigifit, Netherlands

12:00 Discussion and Q&A

12:30 End of Module 3

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"Excellence in Pharmacovigilance" Module 4: Risk Management

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. Examples will be discussed in this session.

Nonetheless, specific data collection and analysis are desirable for some safety issues, and pharmaco-epidemiological studies are the most performed tools of those "additional" Pharmacovigilance activities. This session also presents recent developments regarding risk communication.

Day 1 22 Nov, 08:30-14:00

08:30 Welcome

09:00 Risk Management Plans – Regulatory Perspective: GVP Module V Revision 2

Inge Zomerdijk, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

10:00 Risk Management Plans – Industry Perspective

Jan Petracek, Director, Institute of Pharmacovigilance, Czech Republic

11:00 Break

11:30 Epidemiological Methods and Pharmacovigilance

Fakhredin Sayed Tabatabaei, Senior Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

13:30 Discussion and Q&A

14:00 End of Day 1

Day 2 23 Nov, 09:00-14:00

09:00 Effectiveness of Risk Minimisation Measures – Regulatory Perspective

Inge Zomerdijk, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

10:00 Effectiveness of Risk Minimisation Measures – Industry Perspective

Jan Petracek, Director, Institute of Pharmacovigilance, Czech Republic

11:00 Break

11:30 Harmonisation of RMP (HaRP) in Europe

Paul ten Berg, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

12:30 Risk Communication in EU – Challenges and Possibilities

Jan Petracek, Director, Institute of Pharmacovigilance, Czech Republic

13:30 Discussion and Q&A

14:00 End of Module 4

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"Excellence in Pharmacovigilance" Module 5: Signal Management

New safety signals may emerge at any time following product launch and must be evaluated for relative risk, medical importance, and likelihood of occurrence. Signal Management is, therefore, one of the crucial "routine" Pharmacovigilance activities. Approaches to Signal Management using qualitative and quantitative methods will be illustrated in a workshop with examples as well as general considerations on signal management in the EEA.

Day 1 25 Nov, 08:30-13:00

08:30 Welcome

09:00 Introduction to Signal Detection in the European Union – Regulatory Perspective

Bianca Mulder, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

11:00 Break

11:30 Signal Management in the European Union – Industry Perspective

Jan Petracek, Director, Institute of Pharmacovigilance, Czech Republic

12:30 Discussion and Q&A

13:00 End of Day 1

Day 2 26 Nov, 09:00-11:45

09:00 Signal Management – Workshop

Bianca Mulder, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

11:00 Discussion and Q&A

11:30 Closing Remarks

11:45 End of Module 5