DIA/MEB Excellence in Pharmacovigilance: GVP Modules I to XVI

8-11 October 2024 | Amsterdam, NL

Overview

Organized and delivered in collaboration with the Dutch Medicines Evaluation Board (MEB), this face-to-face interactive training course covers the major pharmacovigilance processes as outlined in GVP I to XVI at intermediate level.

Other than lectures and exercises it gives a lot of room for interaction with the trainers and each other to ensure all your questions are answered. **It is designed to strengthen your foundation in all key aspects of European Post-Marketing Safety regulatory requirements for marketed products as well as marketed products in clinical trials.**

Furthermore, it includes highlights and updates on the pharmacovigilance legislation as well as the latest news on the ICH activities in pharmacovigilance.

Learning Objectives

At the conclusion of this training course, participants will be able to:

- Describe the expedited and periodic ICSR reporting requirements in development and post-marketing
- Discuss the challenges regarding MedDRA and reporting special situations
- Outline the required Quality Management System including PSMF, QPPV, audits and inspections in pharmacovigilance
- List the principles of signal management
- Describe the components of risk management in pharmacovigilance

Who Will Attend

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

Course level: Intermediate

Course Directors

Wendy Huisman
Director
Vigifit, Netherlands

Fakhredin Sayed Tabatabaei
Senior Assessor
MEB, Netherlands

Course Instructors

Negar Babae
Paul ten Berg
Anita Volkers
Fokaline Vroom
Inge Zomerdijk
Pharmacovigilance Assessors
MEB, Netherlands

Liana Martirosyan
PRAC member
EMA/MEB, Netherlands

Anja van Haren
Co-Chair of the EMA EV-EWG & EMA/NCAs Pharmacovigilance Business Team
EMA/MEB, Netherlands

Jan Petracek
CEO
iVigee, Czech Republic

Rodrigo Postigo
Scientific Administrator
EMA, Netherlands

Maris Kuningas
Coordinating Specialist Pharmacovigilance Inspector
Health and Youth Care Inspectorate, Netherlands

Kees Bart Teeuw
Head International PV and Global QPPV
UCB Biopharma, Belgium

Schedule-At-A-Glance

DAY 1

Day 1 corresponds to GVP Modules VI and VII and 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.

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION

08:45 KEYNOTE PRESENTATION

PRAC: PRESENT AND FUTURE OF PHARMACOVIGILANCE

Liana Martirosyan, PRAC member

09:30 COFFEE BREAK

10:00 SESSION 1

EXPEDITED REPORTING REQUIREMENTS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES

Wendy Huisman, Vigifit

Discusses challenges with the concepts and implementation with the aid of interactive discussion around cases studies.

12:30 LUNCH BREAK

13:30 SESSION 2

PREPARATION OF AGGREGATE REPORTS (PSUR AND DSUR)

Kees Bart Teeuw, UCB Biopharma

The content and the relationship between the two aggregate reports.

15:00 COFFEE BREAK

15:30 SESSION 3

REPORTING REQUIREMENTS IN SPECIAL SITUATIONS IN THE POST-AUTHORISATION PHASE

Anja van Haren, EMA/MEB

The do's and don'ts of special situation reports.

16:30 DISCUSSION AND Q&A

17:00 WELCOME RECEPTION

18:00 END OF DAY 1

DAY 2

Day 2 covers GVP Modules I to IV. It gives guidance on the coding with MedDRA and the use of MedDRA queries (SMQs) in assessment.

Furthermore, it covers high level the requirements of the Quality Management System for Pharmacovigilance and includes aspects as well as preparation and conduct of audits and inspections.

08:30 SESSION 4

MEDDRA AND STANDARDISED MEDDRA QUERIES

Fokaline Vroom, MEB

09:45 SESSION 5

PHARMACOVIGILANCE SYSTEM MASTER FILE

Wendy Huisman, Vigifit

10:45 COFFEE BREAK

11:15 SESSION 6

THE ROLE OF THE QUALIFIED PERSON RESPONSIBLE FOR PV

Wendy Huisman, Vigifit

12:00 SESSION 7

AUDITS AND INSPECTIONS IN PHARMACOVIGILANCE - REGULATORY PERSPECTIVE

Maris Kuningas, Health and Youth Care Inspectorate

13:00 LUNCH BREAK

14:00 SESSION 8

QUALITY MANAGEMENT SYSTEM

Wendy Huisman, Vigifit

16:00 DISCUSSION AND Q&A

16:30 END OF DAY 2

DAY 3

Day 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.

08:30 SESSION 9

RISK MANAGEMENT PLANS

Inge Zomerdijk, MEB

Jan Petracek, iVigee

Paul ten Berg, MEB

10:00 COFFEE BREAK

10:30 SESSION 10

EPIDEMIOLOGICAL METHODS AND PHARMACOVIGILANCE

Fakhredin Sayed Tabatabaei, MEB

12:30 LUNCH BREAK

13:30 SESSION 11

EFFECTIVENESS OF RISK MINIMISATION MEASURES

Anita Volkers, MEB

Jan Petracek, iVigee

15:00 COFFEE BREAK

15:30 SESSION 12

RISK COMMUNICATION IN EU – CHALLENGES AND POSSIBILITIES

Jan Petracek, iVigee

16:30 DISCUSSION AND Q&A

17:00 END OF DAY 3

DAY 4

Day 4 covers GVP Modules IX and X.

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 from the industry side, as well as from the regulatory side by EMA and MEB. This will be presented in a workshop with examples as well as general considerations on signal management in the EEA.

08:30 SESSION 13

THE EUROPEAN INFRASTRUCTURE OF SIGNAL MANAGEMENT

Rodrigo Postigo, EMA

09:30 SESSION 14

INTRODUCTION TO SIGNAL DETECTION IN THE EUROPEAN UNION – REGULATORY PERSPECTIVE

Negar Babae, MEB

11:00 COFFEE BREAK

11:30 SESSION 15

SIGNAL MANAGEMENT IN THE EUROPEAN UNION – INDUSTRY PERSPECTIVE

Jan Petracek, iVigee

12:30 LUNCH BREAK

13:30 SESSION 16

SIGNAL MANAGEMENT – WORKSHOP

Negar Babae, MEB

15:30 DISCUSSION AND Q&A

16:00 CLOSING REMARKS

16:15 END OF THE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Venue Information

Holiday Inn Amsterdam Arena Towers
Hoogoorddreef 66A, 1101 BE Amsterdam-Zuidoost, The Netherlands
Tel: +31 20 7979 198
Email: info.amsaa@hiex.nl
Website

Reservations
If you would like to book a bedroom from 7th to 11th October 2024, please click on this Booking Link.

How to get there
On of the largest train stations of Amsterdam; Amsterdam Bijlmer ArenA is located on 5 minute walk of the hotel. When leaving the train station walk along the Heineken Music Hall in south-east direction and you will almost already see the hotel in front of you. Estimated distance to the hotel: 0.25 MI/ 0.4 KM.

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 25 credits.

SwAPP

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

REGISTRATION FORM

DIA/MEB Excellence in Pharmacovigilance # 24548
8-11 October 2024 | Amsterdam, NL

REGISTRATION FEES

Registration fee includes admission to training course, refreshments and electronic access to training course materials.
Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	MEMBER EARLY-BIRD valid until 13 Aug 2024	MEMBER valid from 14 Aug 2024	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 2'475.00 ❑	€ 2'750.00 ❑	€ 3'010.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 1'375.00 ❑	€ 1'635.00 ❑
A special discount is available for organisations which are listed in the EMA SME register: https://fmapps.ema.europa.eu/SME/. Number of discounted seats are limited.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. Tel. :+41 61 225 51 51

Email: **Basel@DIAglobal.org** Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording
If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #24548 as well as the invoice number to ensure correct allocation of your payment.
Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**
By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature