DIA/MEB Excellence in Pharmacovigilance: Good Pharmacovigilance Practices (GVP) Modules I to XVI

14-17 November 2023
Holiday Inn Arena Towers, Amsterdam, The Netherlands

COURSE DIRECTORS

Fakhredin Sayed Tabatabaei
Senior Pharmacovigilance Assessor
Medicines Evaluation Board (MEB), Netherlands

Wendy Huisman
Director
Vigifit, Netherlands

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 end of this training course, participants will be able to:

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

KEY TOPICS

- Post-Marketing: GVP Modules VI and VII
- Regulatory Aspects in Pharmacovigilance: GVP Modules I, II, III and IV
- Risk Management: GVP Modules V, VIII, XV and XVI
- Signal Management: GVP Modules IX and X

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

FACULTY

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

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

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

Jan Petracek
CEO
iVigee, Czech Republic

Vojtech Kvita
Executve Director
NextPV Services, Czech Republic

Rodrigo Postigo
Scientific Administrator
European Medicines Agency, Netherlands

DIA

cBG MEB

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

14 NOV | DAY 1 | POST-MARKETING

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 "The Keyhole of Pharmacovigilance"**
Fakhredin Sayed Tabatabaei, MEB

09:30 COFFEE BREAK

10:00 **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 **Preparation of Aggregate Reports (PSUR and DSUR)**
Vojtech Kvita, NextPV Services
The content and the relationship between the two aggregate reports.

15:00 COFFEE BREAK

15:30 **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**

15 NOV | DAY 2 | REGULATORY ASPECTS IN PV

Day 2 covers GVP Modules I to IV and will provide the safety reporting requirements with case studies from clinical trials with marketed products. 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 **SUSAR Reporting in Clinical Trials and Case Studies**
Wendy Huisman, Vigifit
Discusses challenges with the concepts and implementation with the aid of interactive discussion around cases studies.

10:45 COFFEE BREAK

11:15 **MedDRA and Standardised MedDRA Queries**
Fokaline Vroom, MEB

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

12:45 LUNCH BREAK

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

14:15 **Audits and Inspections in Pharmacovigilance – Regulatory Perspective**
Maris Kuningas, Health and Youth Care Inspectorate

15:15 COFFEE BREAK

15:45 **Quality Management System**
Wendy Huisman, Vigifit

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

18:15 **END OF DAY 2**

Course Venue

Holiday Inn Amsterdam - Arena Towers
Hoogoorddreef 66A
1101 BE Amsterdam-Zuidoost
The Netherlands
Tel: +31 20 7979 198
Email: info.amsaa@hiex.nl
Web: https://www.ihg.com/holidayinn/hotels/us/en/amsterdam/amsaa/hoteldetail

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

Bedroom booking

DIA has booked a limited number of bedrooms for course participants at the rate of EUR 169 per standard room per night including breakfast, excluding fees and VAT.

If you would like to make a booking, please Click Here.

16 NOV | DAY 3 | RISK MANAGEMENT

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 **Risk Management Plans – Regulatory Perspective: GVP Module V Revision 2**
Inge Zomerdijk, MEB

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

10:30 COFFEE BREAK

11:00 **Harmonisation of RMP (HaRP) in Europe**
Fakhredin Sayed Tabatabaei, MEB

11:30 LUNCH BREAK

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

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

15:00 COFFEE BREAK

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

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

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

18:00 **END OF DAY 3**

17 NOV | DAY 4 | SIGNAL MANAGEMENT

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 **The European Infrastructure of Signal Management**
Rodrigo Postigo, EMA

09:30 **Introduction to Signal Detection in the European Union – Regulatory Perspective**
Negar Babae, MEB

11:00 COFFEE BREAK

11:30 **Signal Management in the European Union – Industry Perspective**
Jan Petracek, iVigee

12:30 LUNCH BREAK

13:30 **Signal Management – Workshop**
Negar Babae, MEB

15:30 **Discussion and Q&A**

16:00 **Closing Remarks**

16:15 **END OF THE TRAINING COURSE**

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 Swiss Association of Pharmaceutical Professionals

Group Discount

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

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.
- Group registration is not available online and does not apply to the already discounted fees for industry (early-bird), government or charitable nonprofit/academia

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.

REGISTRATION FORM

Excellence in Pharmacovigilance # 23548

14-17 November 2023 | Amsterdam, The Netherlands

REGISTRATION FEES

Registration fee includes full admission to the training course 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 19 Sep 2023	MEMBER valid from 20 Sep 2023	NON-MEMBER
INDUSTRY	€ 2'340.00 ❑	€ 2'600.00 ❑	€ 2'835.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 1'300.00 ❑	€ 1'535.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information			

***All fees are subject to the 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.

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 CET/CEST.
Tel. :+41 61 225 51 51 **Fax:** +41 61 225 51 52 **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. You agree that your personal data will be transferred to DIA in the US.

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 #23548 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