Joint MEB/DIA training course on

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing

13-17 May 2019
Park Plaza Amsterdam Airport Hotel, Netherlands

OVERVIEW

This course is designed to provide a strong foundation in key aspects of European Clinical Pre- and Post-Marketing Safety regulatory requirements. This five-day training course also includes highlights and updates on the pharmacovigilance legislation and the latest news on the international harmonisation and standardisation activities in pharmacovigilance.

It is also possible to register for each of the 4 course modules separately:

Module 1: Definitions and Methods in Pharmacovigilance

Module 2: Regulatory Aspects in Pharmacovigilance and Practical Examples

Module 3: Signal Management

Module 4: Risk Management

LEARNING OBJECTIVES

Additionnally to the five key topics as outlined below, the learning objectives also include the ability to:

- Understand basic definitions and methods in Pharmacovigilance
- Describe the expedited and periodic ICSRs reporting requirements in clinical trials and post-marketing including the medical evaluation
- Understand the process of audits and inspections in pharmacovigilance
- Understand the principles of signal management
- Describe the components of the risk management

KEY TOPICS

- Definitions and Methods in Pharmacovigilance
- Regulatory Aspects in Pharmacovigilance and Practical Examples
- Diagnosis of Adverse Drug Reactions
- Signal Management
- Risk Management

TARGET AUDIENCE

This course will benefit professionals with basic knowledge and experience in Pharmacovigilance or adjacent functions, for example, PV Officers, PV Specialists, PV Experts, PV Coordinators, Heads/Directors/Managers of Regulatory Compliance, Quality or Safety departments.
Level: Beginner/Intermediate

COURSE DIRECTORS

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Senior Assessor Pharmacovigilance
Medicines Evaluation Board (MEB)
Netherlands

Gaby Danan
Pharmacovigilance Expert, GLD
France

FACULTY

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Assessor Pharmacovigilance, MEB
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INSPECTORATE

Kiki Cheung
Dutch Health Care Inspectorate
Netherlands

Maris Kuningas
Dutch Health Care Inspectorate
Netherlands

DAY 1 | MODULE 1
DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

08:00 REGISTRATION

08:30 INTRODUCTION

Gaby Danan

08:45 KEYNOTE PRESENTATION

Fakhredin Sayed Tabatabaei, MEB

09:15

DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

Module 1 includes a concise overview of the objectives and the scope of Pharmacovigilance. Key definitions based on Community legislation and consensus, such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the CIOMS Working Groups will be explained. Practical examples and exercises will be used to illustrate the basic definitions in Pharmacovigilance and the methods used in Pharmacovigilance.

09:15 Basic Definitions and Tools in Pharmacovigilance
Gaby Danan

10:30 COFFEE BREAK

11:00 Basic Definitions and Tools in Pharmacovigilance continued
Gaby Danan

13:00 LUNCH

14:00 Classical Methods in Pharmacovigilance
Gaby Danan

15:30 COFFEE BREAK

16:00 Epidemiological Methods and Pharmacovigilance
Fakhredin Sayed Tabatabaei, MEB

18:00 NETWORKING RECEPTION

19:00 END OF DAY 1 / MODULE 1

DAY 2 | MODULE 2
REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

08:30

REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

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 in 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 with 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.

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 2

DAY 3 | MODULE 2 CONTINUED

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

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)
Maris Kuningas, Healthcare Inspectorate

14:45 COFFEE BREAK

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

16:00 COFFEE BREAK

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

17:15 END OF DAY 3 / MODULE 2

DAY 4 | MODULE 3
SIGNAL MANAGEMENT

08:30

DIAGNOSIS OF ADVERSE DRUG REACTIONS

Pharmacovigilance is first based on the medical assessment of the adverse events passively or actively collected in organised schemes. It is then essential to be able to identify consistently the nature of events and their seriousness as well as to assess causality with the suspect drug(s). This session will provide basic elements of the medical evaluation of ADRs.

08:30 Medical Evaluation of Adverse Drug Reactions
Gaby Danan

09:30

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. This module will provide approaches to signal detection using quantitative methods illustrated in a workshop with examples as well as general considerations on signal management in the EEA.

09:30 Introduction to Signal Detection
Bianca Mulder, MEB

10:30 COFFEE BREAK

10:45 Signal Management in the European Union: Regulators Perspective
Bianca Mulder, MEB

12:15 LUNCH

13:15 Signal Management in the European Union: Industy Perspective
Jan Petracek

14:00 COFFEE BREAK

14:15 Signal Management – Workshop
Bianca Mulder, MEB
Jan Petracek

15:45 END OF DAY 4 / MODULE 3

DAY 5 | MODULE 4
RISK MANAGEMENT

08:30

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.

This session aims also to provide the background for understanding drug-related risks, and to present recent developments regarding risk communication.

08:30 Risk Communication in EU – Challenges and Possibilities
Jan Petracek

10:00 COFFEE BREAK

10:30 Risk Management Plans: An Industry Perspective
Jan Petracek

12:00 LUNCH

13:00 Harmonisation of RMP (HaRP) in Europe
Paul ten Berg, MEB

14:30 COFFEE BREAK

14:45 Effectiveness of Risk Minimisation Measures
Jan Petracek
Remy Francisca, MEB

16:00 END OF DAY 5 / MODULE 4

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 33.75 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 33.75 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Training Course Venue

Park Plaza Amsterdam Airport Hotel
Melbournestraat 1
1175 RM Lijnden
Netherlands

Accommodation

For more information please visit the website.

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted 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 only available for the industry rate.

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 to DIA.

For groups of 5 or more individuals, please contact Basel@DIAglobal.org for a custom group rate.

REGISTRATION FORM

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing # 19548
13-17 May 2019 | Amsterdam, The Netherlands

REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. 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	NON-MEMBER
INDUSTRY	€ 3'320.00 ❑	€ 3'475.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 1'660.00 ❑	€ 1'815.00 ❑
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 applicable Dutch VAT

Please enter your Company's European VAT number: _____

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

Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.

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 08:00 and 17:00 CET.
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 here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. 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 #19548 as well as the invoice number to ensure correct allocation of your payment.

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