Joint MHRA/DIA training course on

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing

5-9 February 2018
Holiday Inn London - Regent's Park, London, United Kingdom

OVERVIEW

This course is designed to provide a firm grounding 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 Detection and Management

Module 4: Risk Management

LEARNING OBJECTIVES

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

- 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 Detection and Signal Management
  - Modern Technologies and Social Media
- Risk Management

WHO WILL ATTEND

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

Gaby Danan
Pharmacovigilance Expert, France

Phil Tregunno
Signal Management Unit Manager
Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom (UK)

FACULTY

Anna Adams
GPvP Inspector, Inspection, Enforcement & Standards, MHRA, UK

Katherine Donegan
Pharmacoepidemiology, Research & Intelligence Unit Manager, MHRA, UK

Michael Forstner
Managing Director, Head of Risk Management & Business Process Management Practice, Mesama Consulting International, Switzerland

Mick Foy
Group Manager, Vigilance Intelligence and Research Group, MHRA, UK

Louise Larham
Periodic Reports Officer, Global Regulatory Affairs and Safety, Amgen Limited, UK

Amy Marriott
Associate Director – Regulatory Compliance, Janssen Pharmaceutical Research & Development Quality & Compliance, UK

Sophie Reeve
Pharmacovigilance Information Co-ordinator, MHRA, UK

Julie Williams
Expert Assessor, MHRA
PRAC member

DIA

MHRA
Regulating Medicines and Medical Devices

DAY 1 | MODULE 1
DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

08:00 **REGISTRATION**

08:30 **INTRODUCTION**

Gaby Danan, Pharmacovigilance Expert
Phil Tregunno, Signal Management Unit Manager, MHRA

08:45 **KEYNOTE PRESENTATION**

Mick Foy, Group Manager, Vigilance Intelligence and Research Group, MHRA

09:15

DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

Module 1 will provide a concise overview of the objectives and the scope of Pharmacovigilance. The development of 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 summarised. Practical examples and exercises will be used to illustrate the basic key definitions in Pharmacovigilance and the methods used in Pharmacovigilance.

09:15 **Basic Definitions and Tools in Pharmacovigilance**
Gaby Danan, Pharmacovigilance Expert

10:30 COFFEE BREAK

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

13:00 LUNCH

14:00 **Classical Methods in Pharmacovigilance**
Gaby Danan, Pharmacovigilance Expert

15:30 COFFEE BREAK

16:00 **Epidemiological Methods and Pharmacovigilance**
Katherine Donegan, Pharmacoepidemiology, Research & Intelligence Unit Manager, MHRA

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 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.

08:30 **SUSAR Reporting in Clinical Trials and Case Studies**
Gaby Danan, Pharmacovigilance Expert

10:00 COFFEE BREAK

10:30 **SUSAR Reporting in Clinical Trials and Case Studies continued**
Gaby Danan, Pharmacovigilance Expert

12:00 LUNCH

13:00 **The Role of the Qualified Person Responsible for Pharmacovigilance**
Louise Larham, Periodic Reports Officer, Global Regulatory Affairs and Safety, Amgen Limited

13:45 **Preparation of Development Safety Update Reports (DSURs)**
Louise Larham, Periodic Reports Officer, Global Regulatory Affairs and Safety, Amgen Limited

14:30 COFFEE BREAK

14:45 **Preparation of Periodic Safety Update Reports (PSURs)**
Louise Larham, Periodic Reports Officer, Global Regulatory Affairs and Safety, Amgen Limited

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

17:00 COFFEE BREAK

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

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**
Sophie Reeve, Pharmacovigilance Information Co-ordinator, MHRA

12:00 LUNCH

13:00 **Pharmacovigilance System Master File (PSMF)**
Anna Adams, GPvP Inspector, Inspection, Enforcement & Standards, MHRA

13:45 **MedDRA and Standardised MedDRA Queries (SMQs)**
Sophie Reeve, Pharmacovigilance Information Co-ordinator, MHRA

14:45 COFFEE BREAK

15:00 **Audits and Inspections in Pharmacovigilance - Regulatory Perspective**
Anna Adams, GPvP Inspector, Inspection, Enforcement & Standards, MHRA

16:00 COFFEE BREAK

16:15 **Audits and Inspections in Pharmacovigilance - Industry Perspective**
Amy Marriott, Associate Director – Regulatory Compliance, Janssen Pharmaceutical Research & Development Quality & Compliance

17:15 **END OF DAY 3 / MODULE 2**

DAY 4 | MODULE 3
SIGNAL DETECTION AND 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, Pharmacovigilance Expert

09:30

SIGNAL DETECTION AND 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**
Phil Tregunno, Signal Management Unit Manager, MHRA

10:30 **Mobile Technologies and Social Media in Signal Management**
Phil Tregunno, Signal Management Unit Manager, MHRA

11:00 COFFEE BREAK

11:30 **Signal Management in the European Union: Industry Perspective**
Michael Forstner, Managing Director, Head of Risk Management & Business Process Management Practice, Mesama Consulting International

13:00 LUNCH

14:30 **Signal Management – Workshop**
Phil Tregunno, Signal Management Unit Manager, MHRA
Michael Forstner, Managing Director, Head of Risk Management & Business Process Management Practice, Mesama Consulting International

16:00 **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 epidemiological methods that will be described and examples 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**
Michael Forstner, Managing Director, Head of Risk Management & Business Process Management Practice, Mesama Consulting International

10:00 COFFEE BREAK

10:30 **An Overview of the Risk Management Process & the PRAC. The main components of the RMP**
Julie Williams, Expert Assessor, MHRA. PRAC member

12:00 LUNCH

13:00 **Risk Management Plans: An Industry Perspective**
Michael Forstner, Managing Director, Head of Risk Management & Business Process Management Practice, Mesama Consulting International

14:30 COFFEE BREAK

14:45 **Effectiveness of Risk Minimisation Measures**
Michael Forstner, Managing Director, Head of Risk Management & Business Process Management Practice, Mesama Consulting International

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

Holiday Inn London - Regent's Park
Carburton Street
London W1W 5EE
UK
Tel: +44 871 94 29 111
Email: reservations@hiregentspark.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 04 to 09 February 2018 at the rate of GBP 175.00 per standard double room for single use per night including Full English Breakfast, taxes and service fee.
In order to book a hotel room, please contact the hotel directly and quote the booking reference "DIA/SFG".
The room rate is available until 31 December 2017 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE
From Heathrow Airport take the Piccadilly line (Eastbound) and get off at Piccadilly Circus. Change there to Bakerloo line (Northbound) and get off at Regent's Park. The hotel is located within 2 min walk from the Underground station.
From Heathrow Airport take the Heathrow Express to Paddington and change there to Circle or Hammersmith & City line (Eastbound). Get off at Great Portland Street station. The hotel is located within 2 min walk from the Underground station.

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 # 18548
5-9 February 2018 | Holiday Inn London - Regent's Park | London, UK

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 ❑

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 non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

❑ I do not want complimentary 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.

Photography and Video Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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 Fax 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 #18548 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