Joint MHRA/DIA training course on

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing

1–5 February 2016
Holiday Inn 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.

WHO WILL ATTEND

Professionals involved in pharmacovigilance and namely Qualified Persons for Pharmacovigilance (EU QPPV), clinical research, regulatory affairs, risk management, medical product safety assessment, data analysis, epidemiology, labelling, quality assurance, compliance, and medical information.

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

LEARNING OBJECTIVES

For the five key topics as outlined above, 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
- Describe how to be prepared for audits and inspections in pharmacovigilance
- Understand the principles of signal management
- Describe the components of the risk management

CONTINUING EDUCATION

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 32 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 32 credits.

DIA is an authorised training organiation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

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MHRA

COURSE DIRECTORS

Gaby Danan
Pharmacovigilance Expert, France

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

FACULTY

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

Vicki Edwards
QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance
AbbVie Ltd, UK

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

Claire Longman
GPvP Inspector, MHRA, UK

Jan Petracek
CEO, European PharmInvent Services, Czech Republic, Former Head of Risk Management, European Medicines Agency

Jonathan Rowell
Associate Director Regulatory Compliance
Janssen Pharmaceutical Research & Development Quality & Compliance, UK

Sarah Vaughan
Pharmacovigilance Information Unit Manager
MHRA, UK

Margaret Walters
Director & Deputy EU Qualified Person for Pharmacovigilance
Merck Sharp & Dohme Ltd., UK

Julie Williams
Expert Assessor
MHRA, UK
UK PRAC Delegate

DAY 1

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 **TOPIC 1**

DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

Topic 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 key definitions in Pharmacovigilance as well as the classical methods used in Pharmacovigilance in order to detect signals.

09:15 **Topic 1 Session 1**

Basic Definitions and Tools in Pharmacovigilance
Gaby Danan, Pharmacovigilance Expert

10:30 COFFEE BREAK

11:00 **Topic 1 Session 1 continued**

Basic Definitions and Tools in Pharmacovigilance
Gaby Danan, Pharmacovigilance Expert

13:00 LUNCH

14:00 **Topic 1 Session 2**

Classical Methods in Pharmacovigilance
Gaby Danan, Pharmacovigilance Expert

15:30 COFFEE BREAK

16:00 **TOPIC 4**

SIGNAL DETECTION AND SIGNAL MANAGEMENT

16:00 **Topic 4 Session 1**

Introduction to Signal Detection
Phil Tregunno, Signal Management Unit Manager, MHRA

16:45 **TOPIC 5**

RISK MANAGEMENT

16:45 **Topic 5 Session 1**

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

18:15 DRINKS RECEPTION

19:15 **END OF DAY ONE**

DAY 2

08:30 **TOPIC 2**

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). Topic 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 practical case studies.

Aspects that need to be taken into account in establishing a Pharmacovigilance database as well as the key functionalities of the EU's EudraVigilance system will be discussed.

This session will 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 **Topic 2 Session 1**

SUSAR Reporting in Clinical Trials and Case Studies
Gaby Danan, Pharmacovigilance Expert

10:00 COFFEE BREAK

10:30 **Topic 2 Session 1 continued**

SUSAR Reporting in Clinical Trials and Case Studies
Gaby Danan, Pharmacovigilance Expert

12:00 LUNCH

13:00 Topic 2 Session 2

Preparation of Development Safety Update Reports (DSURs)

Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance, AbbVie

Margaret Walters, Director & Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd.

13:45 Topic 2 Session 3

Preparation of Periodic Safety Update Reports (PSURs)

Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance, AbbVie

Margaret Walters, Director & Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd.

14:30 Topic 2 Session 4

The Role of the Qualified Person Responsible for Pharmacovigilance

Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance, AbbVie

Margaret Walters, Director & Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd.

15:15 COFFEE BREAK

15:30 Topic 2 Session 5

Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies

Gaby Danan, Pharmacovigilance Expert

17:00 COFFEE BREAK

17:15 Topic 2 Session 5 continued

Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies

Gaby Danan, Pharmacovigilance Expert

18:15 END OF DAY TWO

DAY 3

08:30 Topic 2 Session 5 continued

Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies

Gaby Danan, Pharmacovigilance Expert

10:15 COFFEE BREAK

10:30 Topic 2 Session 6

Reporting Requirements in Special Situations in the Post-authorisation Phase and Case Studies

Sarah Vaughan, Pharmacovigilance Information Unit Manager, MHRA

12:00 LUNCH

13:00 Topic 2 Session 7

MedDRA and Standardised MedDRA Queries (SMQs)

Sarah Vaughan, Pharmacovigilance Information Unit Manager, MHRA

14:00 Topic 2 Session 8

Pharmacovigilance System Master File (PSMF)

Claire Longman, GPvP Inspector, MHRA

15:00 COFFEE BREAK

15:15 Topic 2 Session 8 continued

Audits and Inspections in Pharmacovigilance - Regulatory Perspective

Claire Longman, GPvP Inspector, MHRA

16:15 COFFEE BREAK

16:30 Topic 2 Session 8 continued

Audits and Inspections in Pharmacovigilance - Industry Perspective

Jonathan Rowell, Associate Director Regulatory Compliance, Janssen Pharmaceutical Research & Development Quality & Compliance, UK

17:30 END OF DAY THREE

DAY 4

08:30 TOPIC 3

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 and as an example what is needed to understand and detect drug-induced liver injury (DILI).

08:30 Topic 3 Session 1

Medical Evaluation of Adverse Drug Reactions

Gaby Danan, Pharmacovigilance Expert

09:30 **Topic 3 Session 2**

Drug-Induced Liver Injury

Gaby Danan, Pharmacovigilance Expert

10:30 COFFEE BREAK

11:00 **Topic 3 Session 2 continued**

Drug-Induced Liver Injury

Gaby Danan, Pharmacovigilance Expert

11:30 **TOPIC 4**

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 session 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.

11:30 **Topic 4 Session 2**

Mobile Technologies and Social Media in Signal Management

Phil Tregunno, Signal Management Unit Manager, MHRA

12:00 LUNCH

13:00 **Topic 4 Session 3**

Signal Management in the European Union: Industry Perspective
Jan Petracek, CEO, PharmInvent

13:30 **Topic 4 Session 4**

Signal Management – Workshop

Phil Tregunno, Signal Management Unit Manager, MHRA

Jan Petracek, CEO, PharmInvent

14:30 COFFEE BREAK

15:00 **TOPIC 5**

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.

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

15:00 **Topic 5 Session 2**

Risk Communication in EU – Challenges and Possibilities

Jan Petracek, CEO, PharmInvent

16:30 **END OF DAY FOUR**

DAY 5

08:30 **TOPIC 1**

DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

08:30 **Topic 1 Session 3**

Epidemiological Methods and Pharmacovigilance

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

10:30 COFFEE BREAK

10:45 **TOPIC 5**

RISK MANAGEMENT

10:45 **Topic 5 Session 3**

Risk Management Plans: An Industry Perspective

Jan Petracek, CEO, PharmInvent

11:45 COFFEE BREAK

12:00 **Topic 5 Session 4**

Post-authorisation Development Plan (PASS/PAES)

Jan Petracek, CEO, PharmInvent

12:30 **Topic 5 Session 5**

Effectiveness of Risk Minimisation Measures

Jan Petracek, CEO, PharmInvent

13:30 **END OF TRAINING COURSE**

Training Course Venue

The training course will take place at:

Holiday Inn Regent's Park
Carburton Street
London, W1W 5EE
Tel: +44 871 942 9111
www.hilondonregentsparkhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 31 January to 5 February 2016 at the rate of GBP 178.00 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 "OPT".

The room rate is available until 27 December 2015 or until the room block is sold-out, whichever comes first.

REGISTRATION FORM

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing # 16548
1-5 February 2016 | Holiday Inn Regent's Park | London, UK

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course 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.

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

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 Europe, Middle East & Africa 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: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa 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 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

email (Required for confirmation) 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 # 16548 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 Europe, Middle East and Africa.**

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