Joint MHRA/DIA training course on

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing

14-18 November 2016
Holiday Inn Kensington Forum, 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.

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

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.

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

Sarah Morgan
Benefit-Risk Management Group Manager
MHRA, UK

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

Sue Rees
EU QPPV, Executive Director, Global Patient Safety
Amgen Ltd, UK

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

Peter Twomey
GPvP Inspector
MHRA, UK

Sarah Vaughan
Pharmacovigilance Information Unit Manager
MHRA, UK

Julie Williams
Expert Assessor
MHRA, UK
UK PRAC Delegate

DIA DEVELOP INNOVATE ADVANCE

MHRA Regulating Medicines and Medical Devices

DAY 1

08:00 **REGISTRATION**

08:30 **INTRODUCTION**

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

08:45 **KEYNOTE PRESENTATION**

Sarah Morgan, Benefit-Risk Management Group Manager, 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 and the methods used in Pharmacovigilance in order to detect signals. The Risk Management process will be described, including the main components of the Risk Management Plan.

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

15:45 **Topic 1 Session 3**

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

16:45 **Topic 1 Session 4**

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

18:15 NETWORKING 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 case studies.

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**

The Role of the Qualified Person Responsible for Pharmacovigilance
Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd.

13:45 **Topic 2 Session 3**

Preparation of Development Safety Update Reports (DSURs)
Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd.

14:30 COFFEE BREAK

14:45 **Topic 2 Session 4**

Preparation of Periodic Safety Update Reports (PSURs)
Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd.

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**

Pharmacovigilance System Master File (PSMF)

Peter Twomey, GPvP Inspector, MHRA

13:45 **Topic 2 Session 8**

MedDRA and Standardised MedDRA Queries (SMQs)

Sarah Vaughan, Pharmacovigilance Information Unit Manager, MHRA

14:45 COFFEE BREAK

15:00 **Topic 2 Session 9**

Audits and Inspections in Pharmacovigilance - Regulatory Perspective

Peter Twomey, GPvP Inspector, MHRA

16:00 COFFEE BREAK

16:15 **Topic 2 Session 9 continued**

Audits and Inspections in Pharmacovigilance - Industry Perspective

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

17:15 **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.

08:30 **Topic 3 Session 1**

Medical Evaluation of Adverse Drug Reactions

Gaby Danan, Pharmacovigilance Expert

09:30 **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.

09:30 **Topic 4 Session 1**

Mobile Technologies and Social Media in Signal Management

Phil Tregunno, Signal Management Unit Manager, MHRA

10:00 COFFEE BREAK

10:30 **Topic 4 Session 2**

Signal Management in the European Union: Industry Perspective

Jan Petracek, CEO, PharmInvent

12:00 LUNCH

13:30 **Topic 4 Session 3**

Signal Management – Workshop

Phil Tregunno, Signal Management Unit Manager, MHRA

Jan Petracek, CEO, PharmInvent

15:00 COFFEE BREAK

15:30 **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 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.

15:30 **Topic 5 Session 1**

Risk Communication in EU – Challenges and Possibilities

Jan Petracek, CEO, PharmInvent

17:00 **END OF DAY FOUR**

DAY 5

08:30 **Topic 5 Session 2**

Epidemiological Methods and Pharmacovigilance

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

10:30 COFFEE BREAK

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**

Follow **@DrugInfoAssn**

Training Course Venue

The training course will take place at:

Holiday Inn Kensington Forum
97 Cromwell Road
London SW7 4DN
United Kingdom
www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 13 to 18 November 2016 at the rate of GBP 160.00 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/ZXL".

The room rate is available until 10 October 2016 or until the room block is sold-out, whichever comes first.

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College 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.

SwAPP Swiss Association of Pharmaceutical Professionals

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

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

REGISTRATION FORM

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing # 16558
14-18 November 2016 | Holiday Inn Kensington Forum | 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 # 16558 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