Regulatory Aspects in Pharmacovigilance and Practical Examples

6-7 February 2018
Holiday Inn London - Regent's Park London, United Kingdom

COURSE DIRECTORS

Gaby Danan
Pharmacovigilance Expert, France

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

OVERVIEW

This Module is part of the MHRA/DIA Excellence in Pharmacovigilance **training course**

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.

DIA

MHRA
Regulating Medicines and Medical Devices

TUESDAY, 6 FEBRUARY
REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

08:00 **REGISTRATION**

08:30

REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

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 1**

WEDNESDAY, 7 FEBRUARY

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 2 / MODULE 2**

REGISTRATION FORM

Regulatory Aspects in Pharmacovigilance and Practical Examples # 18152
6-7 February 2018 | Holiday Inn London - Regent's Park | London, United Kingdom

REGISTRATION FEES

Registration fee includes refreshment breaks, lunch 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	LENGTH	INDUSTRY		GOV/ACA/CHAR	
		MEMBER	NON-MEMBER	MEMBER	NON-MEMBER
MODULE 1: DEFINITIONS AND METHODS IN PHARMACOVIGILANCE	1 day	€ 800.00 ❑	€ 955.00 ❑	€ 400.00 ❑	€ 555.00 ❑
MODULE 2: REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES	**2 days**	**€ 1'450.00 ❑**	**€ 1'605.00 ❑**	**€ 725.00 ❑**	**€ 880.00 ❑**
MODULE 3: SIGNAL DETECTION AND SIGNAL MANAGEMENT	1 day	€ 800.00 ❑	€ 955.00 ❑	€ 400.00 ❑	€ 555.00 ❑
MODULE 4: RISK MANAGEMENT	1 day	€ 800.00 ❑	€ 955.00 ❑	€ 400.00 ❑	€ 555.00 ❑

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 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 #18152 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