Regulatory Aspects in Pharmacovigilance and Practical Examples

3-4 October 2017
The Crystal, London, United Kingdom

COURSE DIRECTORS

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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, 3 OCTOBER
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, 4 OCTOBER

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)**
Zuzana Chomatova, Inspector, Pharmacovigilance department, SUKL

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**
Zuzana Chomatova, Inspector, Pharmacovigilance department, SUKL

16:00 COFFEE BREAK

16:15 **Audits and Inspections in Pharmacovigilance - Industry Perspective**
Amy Marriott, Manager - Regulatory Compliance, J&J BioResearch Quality & Compliance speaker invited

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

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REGISTRATION FORM

Regulatory Aspects in Pharmacovigilance and Practical Examples # 17152
3-4 October 2017 | The Crystal | 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 ❑

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

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Please complete in block capital letters or attach the attendee's business card here.

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Last Name

First Name

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City

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Attendee email required for course material access

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Date	Signature

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