Excellence in Pharmacovigilance: Clinical Trials and Post Marketing

Course #10533
October 25-29, 2010
The Imperial Riding School Renaissance Hotel, Vienna, Austria

Programme Committee

Sabine Brosch
Business Lead EudraVigilance and International Standardisation in Pharmacovigilance
Business Co-ordination and Scientific Projects
Pharmacovigilance and Risk Management Sector
European Medicines Agency, EU

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Former EU Qualified Person for Pharmacovigilance
sanofi-aventis, Pharmacovigilance Expert, France

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William Gregory
Director, Safety and Risk Management, Pfizer,
USA

Nick Phillips
Inspections Manager, Roche Products Ltd., UK

Jan-Willem van der Velden
Director, Mesama Consulting, Switzerland

Patrice Verpillat
Risk Management Plan Officer, sanofi-aventis, France

**This course has limited capacity.
Register early.**

Training Course in Pharmacovigilance presented by the European Medicines Agency

Course Overview

This course is designed to provide a firm grounding in key aspects of Global Clinical Pre and Post Marketing Safety. This five-day training course, presented by the European Medicines Agency, is the only one of its kind.

Who Will Attend - Intermediate Level

Professionals involved in pharmacovigilance, clinical research, regulatory affairs, risk management, medical product safety assessment, and data analysis, epidemiology, labelling, quality assurance, compliance, medical information.

Learning Objectives

Definitions and Methods in Pharmacovigilance

- Describe the scope and objectives of Pharmacovigilance and Risk Management and the relationship between the two concepts
- Discuss the development of definitions based on legislation and consensus fora
- Identify the key definitions and the vocabulary used in Pharmacovigilance in the European Union, illustrated by practical examples and exercises

Regulatory Aspects in Pharmacovigilance and Practical Examples

- Describe the European regulatory requirements in Pharmacovigilance
- Identify the key differences to regulatory requirements in the US and Japan taking into account the international dimension of Pharmacovigilance
- Describe the requirements of establishing a Pharmacovigilance database and the use of MedDRA including the key functionalities of EudraVigilance and AERS
- Discuss good Pharmacovigilance practices and the preparation for audits and inspections

Diagnosis and Management of Adverse Drug Reactions

- Discuss the key elements of the medical evaluation of adverse events
- Recognise the important aspects in evaluating adverse events based on the main system organ classes
- Identify the main characteristics of drug induced adverse events

Risk Management

- Explain the EU risk management strategy, the new approaches to risk assessment and prevention, and the different steps to be considered in the risk management process
- Describe the components of the EU Guideline on the risk management system, focussing on Pharmacovigilance and risk minimisation plans
- Define the concept of risk, and explain differences between individual and population risks
- Explain and illustrate methods used in pharmacoepidemiology for measuring risks and estimating their association with drug exposure
- Describe current recommendations and practices of benefit-risk assessment, review methods for quantitative benefit-risk analysis and discuss their practical application in decision making

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MONDAY | OCTOBER 25, 2010

07:45 Registration

08:25 Introduction
Gaby Danan, Former EU QPPV sanofi-aventis, Pharmacovigilance Expert, France
Sabine Brosch, European Medicines Agency, EU

08:30 TOPIC 1
DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

Overview of Topic 1:
Topic 1 will provide a concise overview of the objectives and the scope of Pharmacovigilance and Risk Management and the relationship between the two concepts. The development of key definitions based on Community legislation and consensus fora such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the CIOMS Working Groups will be summarised. Practical examples and exercises will be used to illustrate the key definitions and vocabulary applied in Pharmacovigilance.

08:30 Keynote Presentation
The Role of the European Medicines Agency in Pharmacovigilance
Sabine Brosch, European Medicines Agency, EU

09:30 Topic 1 Session 1
Basic Definitions and Tools (including ICH and CIOMS Standards)
Anne-Marie de Ferran, sanofi-aventis, France

10:30 Coffee Break

11:00 Topic 1 Session 1 continued
Basic Definitions and Tools (including ICH and CIOMS Standards)
Anne-Marie de Ferran, sanofi-aventis, France

13:00 Lunch

14:00 Topic 1 Session 2
Classical Methods in Pharmacovigilance
Thomas Steinbach, Former QPPV Wyeth and Pharmacovigilance Expert, UK

16:00 Coffee Break

16:30 TOPIC 2
REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

Overview of Topic 2:
The roles and responsibilities of marketing authorisation holders and national Competent Authorities in the conduct of Pharmacovigilance are defined in Community legislation and further detailed in Volume 9A of the 'Rules Governing Medicinal Products in the European Union and Guidelines on Pharmacovigilance for Medicinal Products for Human Use'. Topic 2 will provide a concise summary of the adverse reaction reporting requirements of marketing authorisation holders in the post-authorisation phase and illustrations based on practical case studies.

Furthermore, the roles and responsibilities of sponsors of interventional clinical trials in line with the implementing texts published in relation to Directive 2001/20/EC are summarised.

Taking into account the international dimension of Pharmacovigilance, the session will further address key differences in the regulatory environment of the US and Japan. Aspects that need to be taken into account in establishing a Pharmacovigilance database, the use of MedDRA as well as the key functionalities of the EU's EudraVigilance system and the FDA's Adverse Event Reporting System (AERS) will be discussed.

The main elements will be provided for the establishment of quality system assurance in Pharmacovigilance including aspects of good Pharmacovigilance practices, the elaboration of Standard Operating Procedures (SOPs) and the preparation for audits and inspections.

16:30 Topic 2 Session 1
SUSAR Reporting in Interventional Clinical Trials and Case Studies
Thomas Steinbach, Former QPPV Wyeth and Pharmacovigilance Expert, UK
Sabine Brosch, European Medicines Agency, EU

18:00 End of day 1

18:00 Reception

TUESDAY | OCTOBER 26, 2010

08:30 Topic 2 Session 1 continued
SUSAR Reporting in Interventional Clinical Trials and Case Studies
Thomas Steinbach, Former QPPV Wyeth and Pharmacovigilance Expert, UK
Sabine Brosch, European Medicines Agency, EU

10:00 Coffee Break

10:30 Topic 2 Session 2
Preparation of Annual Safety Reports (ASRs)
Barry Arnold, AstraZeneca, UK

11:15 Topic 2 Session 3
Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies
William Gregory, Pfizer, USA
Sabine Brosch, European Medicines Agency, EU

13:00 Lunch

14:00 Topic 2 Session 3 continued
Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies
William Gregory, Pfizer, USA
Sabine Brosch, European Medicines Agency, EU

16:00 Coffee Break

16:30 Topic 2 Session 4
Preparation of Periodic Safety Update Reports (PSURs)
Barry Arnold, AstraZeneca, UK

17:15 Topic 2 Session 5
The Role of the Qualified Person Responsible for Pharmacovigilance
Barry Arnold, AstraZeneca, UK

18:15 End of day 2

WEDNESDAY | OCTOBER 27, 2010

08:30 **Topic 2 Session 6**
Reporting Requirements in Special Situations in the Post-authorisation Phase and Case Studies
William Gregory, Pfizer, USA

10:30 **Coffee Break**

11:00 **Topic 2 Session 7**
Key Differences in the Pharmacovigilance Regulatory Environment in the US and Japan
William Gregory, Pfizer, USA

12:30 **Lunch**

13:30 **Topic 2 Session 8**
Detailed Description of the Pharmacovigilance System
Sabine Brosch, European Medicines Agency, EU

15:30 **Coffee Break**

16:00 **Topic 2 Session 8 continued**
Audits and Inspections in Pharmacovigilance
Nick Phillips, Roche Products Ltd., UK

17:30 **End of day 3**

THURSDAY | OCTOBER 28, 2010

08:30 **TOPIC 3**
DIAGNOSIS AND MANAGEMENT OF ADVERSE DRUG REACTIONS

Overview of Topic 3:
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, their seriousness, their expectedness and to assess causality with the suspect drug(s). This session will provide clues for the recognition of the serious events involving the main target organs or systems of drug toxicity.

08:30 **Topic 3 Session 1**
Medical Evaluation of Adverse Drug Reactions
Gaby Danan, Former EU QPPV sanofi-aventis, Pharmacovigilance Expert, France

09:30 **Topic 3 Session 2**
Drug-induced Liver Injury: Definitions
Gaby Danan, Former EU QPPV sanofi-aventis, Pharmacovigilance Expert, France

10:30 **Coffee Break**

11:00 **Topic 3 Session 2 continued**
Drug-induced Liver Injury: Causality Assessment
Gaby Danan, Former EU QPPV sanofi-aventis, Pharmacovigilance Expert, France

11:30 **Topic 3 Session 3**
QT/QTc Prolongation and the Risk of Torsade de Pointes
Thomas Steinbach, Former QPPV Wyeth and Pharmacovigilance Expert, UK

12:30 **Lunch**

13:30 **Topic 3 Session 4**
How to Use MedDRA in Adverse Reaction Reporting and Data Analysis
William Gregory, Pfizer, USA

14:15 **Topic 3 Session 5**
Overview of Quantitative Methods for Signal Detection
Thomas Steinbach, Former QPPV Wyeth and Pharmacovigilance Expert, UK
Jan-Willem van der Velden, Mesama Consulting, Switzerland

15:00 **Topic 3 Session 5 continued**
Signal Detection at the Agency
Jan Petracek, European Medicines Agency, EU

16:00 **Coffee Break**

16:30 **TOPIC 4**
RISK MANAGEMENT

Overview of Topic 4:
In accordance with the European Guideline on Risk Management System, risk management plans (RMPs) are now 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, to review epidemiological methods for detecting signals and assessing risks, and to present recent developments regarding risk communication.

16:30 **Topic 4 Session 1**
Risk Management Components: General Principles
Jan Petracek, European Medicines Agency, EU

17:45 **End of Day 4**

FRIDAY | OCTOBER 29, 2010

08:00 **Topic 4 Session 2**
Risk Management Plans: An Industry Perspective
Patrice Verpillat, sanofi-aventis, France

09:00 **Topic 4 Session 3**
Discussion on Risk Management Plans
Patrice Verpillat, sanofi-aventis, France
Jan Petracek, European Medicines Agency, EU

09:30 **Coffee Break**

10:00 **Topic 4 Session 4**
Epidemiological Methods and Pharmacovigilance
Patrice Verpillat, sanofi-aventis, France

12:00 **Lunch**

13:00 **Topic 4 Session 5**
Risk Communication in EU - Challenges and Possibilities
Jan Petracek, European Medicines Agency, EU

14:30 **Topic 4 Session 6**
Risk Management in Special Circumstances: New Developments for Emerging Situations
Jan Petracek, European Medicines Agency, EU

15:30 **End of Training Course**

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the:

The Imperial Riding School
Rennaissance Hotel
Ungargasse 60 - 1030 Vienna, Austria

Tel.: +43 1 711 75 0 - Fax: +43 1 711 75 8143
Website: www.imperialrenaissance.com

at the special rate of
EUR 109.00 for a room in single occupancy and
EUR 129.00 for double occupancy.

The above rates include American Buffet Breakfast, service, taxes and free access to indoor pool and fitness area.
To reserve a room, please use the online booking link on the DIA website or call the hotel mentioning "DIA" in order to profit of the preferential rate.

IMPORTANT: To be assured of accommodation at the Imperial Riding School Renaissance Hotel, registrants are recommended to complete their reservation by September 13, 2010.

REGISTRATION FORM

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing

October 25-29, 2010 - The Imperial Riding School Renaissance Hotel, Vienna, Austria

ID# 10533

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

CATEGORY	MEMBER			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 20%	TOTAL	FEE	VAT 20%	Membership	TOTAL	FEE	VAT 20%	TOTAL
Industry	€ 2'961.00	€ 592.20	**€ 3'553.20** ❑	€ 2'961.00	€ 592.20	€ 115.00	**€ 3'668.20** ❑	€ 3'076.00	€ 615.20	**€ 3'691.20** ❑
Government/Academia (Full-Time)	€ 1'481.00	€ 296.20	**€ 1'777.20** ❑	€ 1'481.00	€ 296.20	€ 115.00	**€ 1'892.20** ❑	€ 1'596.00	€ 319.20	**€ 1'915.20** ❑

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the course

Please indicate your areas of professional interest

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- ❑ AH - Academic Health Centres
- ❑ AM - Alternative / Herbal Medicine
- ❑ BT - Biotechnology
- ❑ CD - Clinical Data Management
- ❑ CH - Chemistry / Drug Design
- ❑ CL - Clinical Laboratory Data
- ❑ CM - CMC
- ❑ CP - Clinical Safety/Pharmacovigilance
- ❑ CR - Clinical Research & Development
- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
- ❑ DE - Devices
- ❑ DM - Document Management
- ❑ FI - Finance
- ❑ EC - e-Clinical
- ❑ GC - GCP
- ❑ GE - Generic Manufacturing
- ❑ GL - GLP
- ❑ GM - GMP
- ❑ IM - Information Management
- ❑ IMP - Impact
- ❑ IS - Investigator Site
- ❑ IT - Information Technology / e-Business
- ❑ LA - Legal Affairs
- ❑ MA - Marketing / Advertising
- ❑ MC - Medical Communications / Information
- ❑ MH - Managed Healthcare
- ❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
- ❑ MW - Medical / Scientific Writing
- ❑ NC - Non-clinical Safety & Efficacy / Toxicology
- ❑ NH - Natural Health Products
- ❑ OS - Outsourcing / Virtual Development
- ❑ OT - Over the Counter
- ❑ PC - Pharmaceutics
- ❑ PD - Professional Development
- ❑ PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- ❑ PH - Pharmacology
- ❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- ❑ PM - Project Management
- ❑ PP - Public Policy / Law
- ❑ QC- Quality Control / Quality Assurance
- ❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- ❑ RD - Research & Development / Strategic Issues
- ❑ ST - Statistics / Biostatistics / Mathematical Modelling
- ❑ TR - Training
- ❑ VA - Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

PAYMENT METHODS

❑ **Please charge my credit card** - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ **VISA** ❑ **MC** ❑ **AMEX**

Card Number

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Date Cardholder's Signature

❑ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ **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." including your name, company, Meeting ID# 10533 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.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee: Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Registrants who do not cancel five working days prior to the course start date and do not attend, will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants 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 registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.**

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA European Office Postfach, 4002 Basel, Switzerland