Excellence in Pharmacovigilance: Clinical Trials and Post Marketing

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

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

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

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

Thomas Goedecke
Patient Health Protection Unit
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Wyeth and Pharmacovigilance Expert, UK

Programme Faculty
Barry Arnold
EU Qualified Person for Pharmacovigilance,
AstraZeneca, UK

Anne-Marie de Ferran
Head of the Pharmacovigilance Quality & Compliance - Global Pharmacovigilance and Epidemiology, sanofi-aventis R&D, France

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

Jan Petracek
Consultant, PharmInvent, Czech Republic

Nick Phillips
Inspections Manager, Roche Products Ltd., UK

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

Credits
This training course has been awarded with 25 CPD credits from the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom.

This course has limited capacity. Register early.
MONDAY | OCTOBER 25, 2010

Chairpersons:
Sabine Brosch, Gaby Danan, Thomas Steinbach

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

Chairpersons:
Sabine Brosch, Gaby Danan, Thomas Steinbach

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

Chairpersons:
Sabine Brosch, Gaby Danan, Thomas Steinbach

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
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

15:00 Topic 3 Session 5 continued
Signal Detection at the Agency
Thomas Goedecke, European Medicines Agency, EU
Jan Petracek, PharmInvent, Czech Republic

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
Thomas Goedecke, European Medicines Agency, EU

17:45 End of Day 4

FRIDAY | OCTOBER 29, 2010

Chairpersons:
Gaby Danan, Thomas Goedecke, Thomas Steinbach

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
Thomas Goedecke, European Medicines Agency, EU
Jan Petracek, PharmInvent, Czech Republic
Patrice Verpillat, sanofi-aventis, France

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, PharmInvent, Czech Republic

14:30 Topic 4 Session 6
Risk Management in Special Circumstances: New Developments for Emerging Situations
Jan Petracek, PharmInvent, Czech Republic

15:30 End of Training Course

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the:
The Imperial Riding School
Renaissance 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.

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.
REGISTRATION FORM
Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
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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.

Please indicate your areas of professional interest

- 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

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

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- academia
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- 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.

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D.I.A., Elisabethenanalage 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: D.I.A.” 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.

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