EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing training course

Course #12566
1-5 October 2012
Hilton London Docklands Riverside Hotel | London, UK

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Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 25 CPD credits. The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 34.5 credits.

This course has limited capacity. Register early.

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 now also including highlights and updates on the implementation of the new pharmacovigilance legislation and the latest news on the international harmonisation and standardisation activities in pharmacovigilance.

Who Will Attend

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

Learning Objectives

For the five key topics as outlined below, the learning objectives now also include the ability to:
- Describe the main changes to the business processes in the context of the new pharmacovigilance legislation
- Discuss the latest developments in the area of international harmonisation and standardisation with main focus on the ICH E2B, E2C, E2F topics and the ISO Identification of Medicinal Products (IDMP) standards

At the conclusion of this course, participants should be able to:

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

Signal Detection
- Understand MedDRA dictionary
- Describe signal detection and management in the EU

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

EUROPEAN MEDICINES AGENCY
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MONDAY | 1 OCTOBER 2012

08:00 REGISTRATION

08:45 Keynote Presentation
The Role of the European Medicines Agency in Pharmacovigilance
Sabine Brosch, European Medicines Agency, EU

09:45 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.

09:45 Topic 1 Session 1
Basic Definitions and Tools (including ICH and CIOMS Standards)
Gaby Danan, Pharmacovigilance Expert, France

10:45 COFFEE BREAK

11:15 Topic 1 Session 1 continued
Basic Definitions and Tools (including ICH and CIOMS Standards)
Gaby Danan, Pharmacovigilance Expert, France

13:15 LUNCH

14:15 Topic 1 Session 2
Classical Methods in Pharmacovigilance
Gaby Danan, Pharmacovigilance Expert, France

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 EU legislation and further detailed in Good Vigilance Practices (GVP). 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.

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 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
Sabine Brosch, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

18:00 DRINKS RECEPTION

19:00 END OF DAY 1

TUESDAY | 2 OCTOBER 2012

08:30 Topic 2 Session 1 continued
SUSAR Reporting in Interventional Clinical Trials and Case Studies
Sabine Brosch, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

10:00 COFFEE BREAK

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

11:15 Topic 2 Session 3
Preparation of Periodic Safety Update Reports (PSURs)
Barry Arnold, AstraZeneca, UK

12:15 LUNCH

13:15 Topic 2 Session 4
The Role of the Qualified Person Responsible for Pharmacovigilance
Barry Arnold, AstraZeneca, UK

14:15 Topic 2 Session 5
Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies
Sabine Brosch, European Medicines Agency, EU
William Gregory, Pfizer, USA

15:45 COFFEE BREAK

16:15 Topic 2 Session 5 continued
Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies
Sabine Brosch, European Medicines Agency, EU
William Gregory, Pfizer, USA

18:00 END OF DAY 2

WEDNESDAY | 3 OCTOBER 2012

08:30 Topic 2 Session 5 continued
Expedited Reporting Requirements in the Post-authorisation Phase and Case Studies
Sabine Brosch, European Medicines Agency, EU
William Gregory, Pfizer, USA

10:30 COFFEE BREAK

11:00 Topic 2 Session 6
Reporting Requirements in Special Situations in the Post-authorisation Phase and Case Studies
William Gregory, Pfizer, USA

12:30 LUNCH

13:30 Topic 2 Session 7
Detailed Description of the Pharmacovigilance System
Sabine Brosch, European Medicines Agency, EU

15:30 COFFEE BREAK

16:00 **Topic 2 Session 7 continued**

Audits and Inspections in Pharmacovigilance
Nick Phillips, Roche Products Ltd., UK

17:30 **END OF DAY 3**

THURSDAY | 4 OCTOBER 2012

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 two serious events involving target organs of drug toxicity.

08:30 **Topic 3 Session 1**
Medical Evaluation of Adverse Drug Reactions
Gaby Danan, Pharmacovigilance Expert, France

09:30 **Topic 3 Session 2**
Drug-Induced Liver Injury
Gaby Danan, Pharmacovigilance Expert, France

10:30 **COFFEE BREAK**

11:00 **Topic 3 Session 2 continued**
Drug-Induced Liver Injury
Gaby Danan, Pharmacovigilance Expert, France

11:30 **Topic 3 Session 3**
QT/QTc Prolongation and the Risk of Torsade de Pointes
Gaby Danan, Pharmacovigilance Expert, France

12:30 **LUNCH**

13:30 **TOPIC 4**

SIGNAL DETECTION

Overview of Topic 4
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 an understanding of safety data classification and approaches to signal detection using traditional and quantitative methods.

13:30 **Topic 4 Session 1**
MedDRA and Standardised MedDRA Queries (SMQs)
William Gregory, Pfizer, USA

14:15 **Topic 4 Session 2**
Introduction to Signal Detection
Georgy Genov, European Medicines Agency, EU

15:00 **COFFEE BREAK**

15:30 **Topic 4 Session 3**
Signal Management in the European Union:
- Regulatory Network Perspective
  Georgy Genov, European Medicines Agency, EU
- Industry Perspective
  Jan Petracek, PharmInvent, Czech Republic

16:30 **TOPIC 5**

RISK MANAGEMENT

Overview of Topic 5
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 5 Session 1**
Risk Management Components: General Principles
Thomas Goedecke, European Medicines Agency, EU

17:45 **END OF DAY 4**

FRIDAY | 5 OCTOBER 2012

08:30 **Topic 5 Session 2**
Risk Management Plans: An Industry Perspective
Patrice Verpillat, Sanofi, France

09:30 **Topic 5 Session 3**
Discussion on Risk Management Plans
Thomas Goedecke, European Medicines Agency, EU
Jan Petracek, PharmInvent, Czech Republic
Patrice Verpillat, Sanofi, France

10:00 **COFFEE BREAK**

10:30 **Topic 5 Session 4**
Epidemiological Methods and Pharmacovigilance
Patrice Verpillat, Sanofi, France

12:30 **LUNCH**

13:30 **Topic 5 Session 5**
Risk Communication in EU - Challenges and Possibilities
Jan Petracek, PharmInvent, Czech Republic

15:00 **Topic 5 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 following hotel:

Hilton London Docklands Riverside
265 Rotherhithe Street
SE16 5HW London
United Kingdom

Tel.: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599
Email: reservations.docklands@hilton.com
Website: http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

At the special rate of GBP 169.00 per room inclusive of breakfast, exclusive of VAT.

To make your reservation, please call the reservation team at +44 (0) 207 2311001 and mention
Group Name: Drug Information Association
Group Code: GDIAC

Important: Please complete your reservation by **2 September 2012**. Reservations received after this date will be subject to hotel availability and room rate may vary.

REGISTRATION FORM

EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing training course
1-5 October 2012 | Hilton London Docklands Riverside Hotel, London, UK

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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.

CATEGORY	Member Fee	Non-Member Fee
Industry	€ 2'961.00 ❑	€ 3'076.00 ❑
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TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION 12566DIA

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__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
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ATTENDEE DETAILS

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❑ 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 #12566 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.

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
Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you 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 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 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 Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe 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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