How to Prepare for Pharmacovigilance Audits and Inspections

Course #10551
27 April 2010
Marriott Rive Gauche, Paris, France

Course Faculty

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Former Qualified Person for Pharmacovigilance,
Pharmacovigilance Expert, London, United Kingdom

About the Drug Information Association

The DIA is a professional association of approximately 18,000 members worldwide who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. We are committed to the broad dissemination of information on the development of new medicines or generics and biosimilars, with continuously improved professional practice as the goal. The DIA is a financially independent non-profit organisation that funds itself from meeting and membership fees. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications at a reasonable, competitive cost.

This course has limited capacity.
Register early.

Course Overview

Every pharmacovigilance function will, at one time or another, undergo governmental or health authority inspections as well as audits by license partners, internal auditors and others. The course will teach you how to prepare for an audit / inspection from the time of the receipt of the announcement (or of the arrival of the inspectors at your doorstep) to the conclusion of the audit or inspection.

Who Will Attend

Professionals who work in:

- Pharmacovigilance / Drug safety (QPPV)
- Regulatory Affairs
- Quality & Compliance
- Information Technology
- Medical Information
- Risk Management
- Compliance
- Pharmacovigilance Auditors
- Management Staff Responsible for Running Inspections
- Employees (directly and indirectly) Involved in Inspections

Learning Objectives

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

- Participate in audits / inspections and mock audits / inspections.
- Assess how to handle the actual audit / inspection and responses to requests and findings based on
    - the understanding of audit / inspection methodology
    - the legal basis of inspections or
    - the contractual basis of audits and
    - the appreciation of regional differences
- Prepare responses to audit / inspection findings, including responses and corrective/ preventive action (CAPA) plans
- Prepare their function for an audit / inspection: roadmap, teams, tasks, and documents
- Assess regional differences with respect to European and US FDA inspections

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AGENDA

08:30	Registration
09:00	Start of Training Course
	Coffee Break
12:30 – 13:30	Lunch
13:30	Continuation of Training Course
	Coffee Break
17:30	End of Training Course

Session 1

The Basics
Presentation

Session 2

European and FDA Inspections
Presentation

Session 3

Pharmacovigilance Requirements and Findings

Introductory presentation and group work

Session 4

Responding to the Findings and Preparing the CAPA

Introductory presentation and group work

Session 5

Onsite Audit / Inspection

Introductory presentation, group work and role play

Session 6

Preparation for Audits and Inspections

Introductory presentation and group work

Hotel Information

The DIA has blocked a limited number of rooms at the:
Marriott Rive Gauche
17, Blvd. Saint-Jacques
75014 Paris, France

Tel. +33 (0) 1 40 78 79 80 - Fax: +33 (0) 1 45 88 78 05

at the special rate of EUR 159.00 including breakfast, service and VAT tax.

To reserve a room, please book online on the DIA website www.diahome.org

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DIA UPCOMING TRAINING COURSES IN 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

The New Individual Case Safety Report (ICSR) International Standard and ICH E2B/M2 Information Day at the European Medicines Agency
25 June 2010 | London, United Kingdom | ID 10568

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, UK and selected European cities
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on Related Courses

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.

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REGISTRATION FORM

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 - Marriott Rive Gauche, Paris, France

ID# 10551

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 19.6%	TOTAL	FEE	VAT 19.6%	Membership	TOTAL	FEE	VAT 19.6%	TOTAL
Industry	€ 770.00	€ 150.92	**€ 920.92** ❑	€ 770.00	€ 150.92	€ 115.00	**€ 1'035.92** ❑	€ 885.00	€ 173.46	**€ 1'058.46** ❑
Government/Academia (Full-Time)	€ 385.00	€ 75.46	**€ 460.46** ❑	€ 385.00	€ 75.46	€ 115.00	**€ 575.46** ❑	€ 500.00	€ 98.00	**€ 598.00** ❑

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

STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT DIA FOR MORE INFORMATION.
DISCOUNTS AVAILABLE IF BOTH PHARMACOVIGILANCE COURSES ARE ATTENDED ON THE 26TH AND 27TH OF APRIL, 2010

10551DIA

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 - CREDIT CARD PAYMENT IS PREFERRED

❑ **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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❑ **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# 10551 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.

Hotel Information

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17, Blvd. Saint-Jacques
75014 Paris, France
Tel.: + 33 (0) 1 40 78 79 80 - Fax: + 33 (0) 1 40 78 78 05
www.marriott.com

at a special rate of EUR 159.00 per room per night for single occupancy and EUR 169.00 for double occupancy. The rates include buffet breakfast, service and VAT.

Reservations are to be made directly with Marriott reservations at +33 (0) 1 40 DIA EUROPE, using the group code CDPCDPA. You can also use the code in www.marriott.com in the group code section to enable online registrations.

IMPORTANT: In order to profit of the special rate, registrants are recommended to complete their reservation at their earliest convenience at the Marriott Rive Gauche but no later than March 26, 2010.

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