

# How to Prepare for Pharmacovigilance Audits and Inspections

Course #10559

8 October 2010

Park Inn Russell Square, London, UK



## Course Faculty

### Thomas Steinbach

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

## AGENDA

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

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.

### 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:

Park Inn London Russell Square  
92 Southampton Row  
WC1B 4BH London, United Kingdom  
Ph +44 207 400 3808 - Fax +44 207 400 3817  
<http://www.london.russell-square.parkinn.co.uk/>

at the special rate of:

Room in single use GBP 140.00 - Room in double use GBP 150.00

These rates are per room and night and include service, taxes, VAT and buffet Breakfast.

To reserve a room, please use the hotel booking form on the DIA website or call the hotel.

**IMPORTANT:** To be assured of accommodation at the Park Inn Russell Square, registrants are recommended to complete their reservation by 8 September 2010 at the latest. Reservations received after that date are subject to availability.

## Always Stay One Move Ahead With DIA Training Courses



How you, your colleagues and company can benefit:

- Up-to-the-minute knowledge of important industry hot topics and latest developments
- Practical industry and agency case studies
- Expert training from professional faculty actively practising in their particular discipline
- Networking opportunities
- Limited attendance allows for a more personal quality learning experience
- Attend accredited training courses and earn continuing education credits
- Train your whole team: group discounts available

# 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](http://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 | Basel, Switzerland | ID 10563  
14-15 October 2010 | Paris, France | ID 10564

For more information and a complete listing of all training courses, please visit [www.diahome.org](http://www.diahome.org) and click on Training.

# REGISTRATION FORM

How to Prepare for Pharmacovigilance Audits and Inspections

8 October 2010 - Park Inn Russell Square, London, UK

ID# 10559



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	TOTAL	FEE	Membership	TOTAL	FEE	TOTAL
Industry	€ 770.00	€ 770.00 <input type="checkbox"/>	€ 770.00	€ 115.00	€ 885.00 <input type="checkbox"/>	€ 885.00	€ 885.00 <input type="checkbox"/>
Government/Academia (Full-Time)	€ 385.00	€ 385.00 <input type="checkbox"/>	€ 385.00	€ 115.00	€ 500.00 <input type="checkbox"/>	€ 500.00	€ 500.00 <input type="checkbox"/>

**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 7TH AND 8TH OF OCTOBER 2010**

10559DIA

**RESPONSIBILITY/INTEREST AREA** | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

<input type="checkbox"/> Advertising & Promotion	<input type="checkbox"/> Medical Communications	<input type="checkbox"/> Pharmacology	<input type="checkbox"/> Regulatory Aff airs
<input type="checkbox"/> CMC	<input type="checkbox"/> Medical Writing	<input type="checkbox"/> Pricing/Reimbursement	<input type="checkbox"/> Research & Development
<input type="checkbox"/> Clinical Data Management/ eClinical	<input type="checkbox"/> Nonclinical	<input type="checkbox"/> Project Management	<input type="checkbox"/> Statistics
<input type="checkbox"/> Clinical Research	<input type="checkbox"/> Outsourcing	<input type="checkbox"/> Professional Education, Training &	<input type="checkbox"/> Strategic Planning
<input type="checkbox"/> Clinical Safety/Pharmacovigilance	<input type="checkbox"/> Comparative Effectiveness/Health	<input type="checkbox"/> Development	<input type="checkbox"/> IT/Validation
<input type="checkbox"/> Document Management/ eSubmissions	<input type="checkbox"/> Technology Assessment/Evidence-based	<input type="checkbox"/> Public Policy/Law/Corp. Compliance	
<input type="checkbox"/> Manufacturing	<input type="checkbox"/> Medicine	<input type="checkbox"/> Quality Assurance/Quality Control	

## REGISTRANT

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

☐ Prof. ☐ Dr. ☐ Ms. ☐ Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code

City

Country

Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

**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.

☐ VISA ☐ MC ☐ AMEX

Card Number

Exp. Date

Cardholder's Name

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., Elisabethen Anlage 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# 10559 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](http://www.diahome.org)

**Fax** +41 61 225 51 52

**Email** [diaeurope@diaeurope.org](mailto:diaeurope@diaeurope.org)

**Mail** DIA European Office  
Postfach, 4002 Basel, Switzerland