DIA Training Course on

How to Prepare for Pharmacovigilance Audits and Inspections

Course #12575
15-16 November 2012
Radisson Blu Alcron Hotel, Prague, Czech Republic

Faculty

Nick Phillips
Head of Inspections Management, PDQA
Roche Products Ltd., UK

MHRA representative invited

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

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

Course Level

For professionals with 2-3 years of experience in pharmacovigilance this course will be at an intermediate level; professionals with experience from the auditing area will find this course to be at a beginner level.

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
  - o the understanding of audit / inspection methodology
  - o the legal basis of inspections or
  - o the contractual basis of audits and
  - o 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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THURSDAY | 15 NOVEMBER 2012

13:30	REGISTRATION
14:00	Training course session
15:30	COFFEE BREAK
16:00	Training course session
18:30	END OF DAY ONE

FRIDAY | 16 NOVEMBER 2012

08:30	Training course session
10:30	COFFEE BREAK
11:00	Training course session
13:00	LUNCH
14:00	Training course session
15:30	END OF TRAINING COURSE

About DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide educational publications.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

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 following hotel:

Radisson Blu Alcron Hotel
Stepanska 40
110 00 Praha 1, Czech Republic
Email: iveta.hazdova@radissonblu.com
Tel: +420 222 820 058
Fax: +420 222 820 120

at the special rate of 3'000 Czech Koruna per room inclusive of buffet breakfast, internet and free access to fitness and sauna, exclusive of 14% VAT.

In order to make your reservation please use the hotel booking form available on the DIA website.

Important: Please complete your reservation by 13 September 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

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

Speakers and agenda are subject to change without notice.
Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

DIA UPCOMING TRAINING COURSES IN 2012

Chemistry, Manufacturing and Controls (CMC) / Quality

Chemistry, Manufacturing & Controls (CMC)
22-24 October 2012 | Vienna, Austria | ID 12579

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
25-27 November 2012 | Dubai, United Arab Emirates | ID 12550

Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators
24-26 September 2012 | Vienna, Austria | ID 12573

Clinical Research

Advanced GCP Study Monitoring
5 November 2012 | Paris, France | ID 12585

Clinical Project Management – Part I
3-5 December 2012 | Vienna, Austria | ID 12572

Clinical Statistics for Non-Statisticians
25-26 October 2012 | Nice, France | ID 12567

Essentials of Clinical Study Management
14-16 November 2012 | Paris, France | ID 12570

Practical GCP Compliance Auditing of Trials and Systems
17-19 October 2012 | London, United Kingdom | ID 12568

Non-Clinical Safety Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
19-23 November 2012 | Lisbon, Portugal | ID 12571

Regulatory Affairs

Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe
17-19 September 2012 | Basel, Switzerland | ID 12559

European Regulatory Affairs: In-depth review of current registration procedures in the European Union
15-16 November 2012 | Paris, France | ID 12569

Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects as used in personalised medicine
26-28 November 2012 | Amsterdam, The Netherlands | ID 12576

Health Authority Interactions – Preparation, consultation and implementation
25-26 September 2012 | Basel, Switzerland | ID 12552

Health Technology Assessment (HTA)
20-21 November 2012 | Zurich, Switzerland | ID 12578

US Regulatory Affairs: A Comprehensive Review of Regulatory Procedures for INDs and NDAs in the US
5-7 November 2012 | Paris, France | ID 12586

Safety and Pharmacovigilance

Benefit/Risk Management
15–16 October 2012 | Paris, France | ID 12594

EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing
1-5 October 2012 | London, United Kingdom | ID 12566

EudraVigilance Information Day at the European Medicines Agency
5 October 2012 | London, United Kingdom | ID 12534

How to Prepare for Pharmacovigilance Audits and Inspections
15-16 November 2012 | Prague, Czech Republic | ID 12575

IDMP Information Day at the European Medicines Agency
4 December 2012 | London, United Kingdom | ID 12536

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
16 October 2012 | London, United Kingdom | ID 12539
20 November 2012 | London, United Kingdom | ID 12540

Introduction to Signal Detection and Data Mining in Pharmacovigilance
14-15 November 2012 | Prague, Czech Republic | ID 12574

Medical Approach in Diagnosis and Management of ADRs
15–16 October 2012 | Paris, France | ID 12565

EudraVigilance (EV) - Electronic reporting of ICSR
eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org >
Training > EudraVigilance > Click on > Related Courses

DIA Tailored Training

DIA Tailored Training is a highly flexible, efficient and cost-effective way to get the maximum return on your training investment. Schedule your training course when it suits you best, at the venue of your choice. You can even adapt the content to include areas specific to your environment, and to match the level of expertise of the audience. DIA Tailored Training is available to both public and private institutions and is delivered by instructors with no conflict of interest.
The DIA Tailored Training programmes in Europe make the most of a selection of world-class expert faculty who are experienced professionals in the pharmaceutical and related industries.

Contact DIA Europe to discuss your organisation's requirements.

REGISTRATION FORM

How to Prepare for Pharmacovigilance Audits and Inspections
15-16 November 2012 | Radisson Blu Alcron Hotel, Prague, Czech Republic

ID #12575

DIA www.diahome.org

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	€ 1'155.00 ❑	€ 1'270.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 578.00 ❑	€ 693.00 ❑

*All fees are subject to Czech VAT of 20%

Join DIA now to qualify for the member rate — Fee € 115.00 ❑

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 12575DIAWEB

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.

__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'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

Please enter your company's European VAT number: _____

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

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ 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

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Kuechengasse 16, 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 #12575 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.

Online	Fax	Email	Mail
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