DIA Training Course on

How to Prepare for Pharmacovigilance Audits and Inspections

Course #13556 7-8 November 2013 Hotel Mercure Paris la Villette, France



Faculty

Nick Phillips

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

MHRA representative invited

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

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.

PharmaTrain recognised

PharmaTrain

* MASTERING MEDICINES DEVELOPMENT



THURSDAY | 7 NOVEMBER 2013

13:30 REGISTRATION

14:00 Training course session

15:30 COFFEE BREAK

16:00 Training course session

18:30 END OF DAY ONE

FRIDAY | 8 NOVEMBER 2013

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

Hotel Information

DIA has blocked a limited number of rooms at the following hotel:

Mercure Paris la Villette

216 Avenue Jean Jaurès

75019 Paris

France

Tel:+33 (0) 1 44 84 18 18

Fax:+33 (0) 1 44 84 18 20

 ${\bf Email: mercure parisv@alliance-hospitality.com}$

Website: http://www.mercure.com/fr/hotel-8816-mercure-paris-la-villette/index.shtml

at the rates of EUR 180.00 per room inclusive of breakfast and VAT.

To make your reservation, please use the hotel booking from available on the DIA website.

Important: The room rate is available until 22 September or until the group block is sold-out, whichever comes first.

Cancellation policy

No change or cancellation can be made after booking.

The client acknowledges that first night of the stay will be charged when the booking is made. This amount is non-refundable.

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

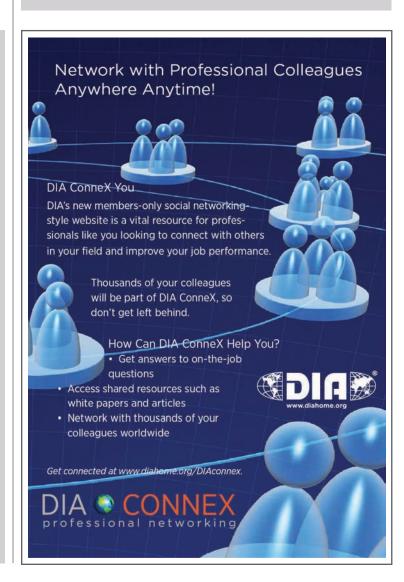
Introductory presentation, group work and role play

Session 6

PREPARATION FOR AUDITS AND INSPECTIONS

Introductory presentation and group work

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 during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.



REGISTRATION FORM

DIA Training Course on how to Prepare for Pharmacovigilance Audits and Inspections 7-8 November 2013 I Hotel Mercure Paris la Villette, France



FEES		М	ember*	Non-Member*
Industry		€ 1'155	.00 🗖	€ 1′270.00 🗖
Academia/Charitable/Government/Non-profit (Full-time)		€ 578	.00 🗖	€ 693.00 □
Join DIA now to qualify for the member rate			€ 115.	00 🗖
*All fees will be subject to the French VAT at 19.6 $\%$	If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.			
Please advise your European VAT number:	Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.			
	Registration fee includes: refreshments, lunches and training course material.			
TOTAL AMOUNT DUE:	Payment is due 30 days after registration and must be paid in full by commencement of the course.			
ATTENDEE DETAILS	PAYMENT METH	HODS		
Please complete in block capital letters or attach the attendee's business card here.	Credit cards: Payments by VIS. details below. Please note that of	*		
□ Prof □ Dr □ Ms □ Mr	☐ Please charge my ☐ VISA	□ MC □ AMEX		
Last Name	Card N°			
First Name				
Company	Exp. Date			
Job Title	Cardholder's Name			
Address				
Postal Code City	☐ Bank transfers: When DIA of address on the registration transfer. Payments in EURO include your name, company,	form with instructionshould be addressed Course ID # 13556 as well as the state of	ns on how to to "Account	o complete the bank Holder: DIA." Please
Country	correct allocation of your page	yment.		
Telephone	Payments must be net of all charges and bank charges must be borne by the payer. If you have not received your confirmation within five working days, please contact DIA Europe.			
Fax				
Email*	By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms			
*(Required for confirmation)	Date	Signature		
DIA reserves the right to include your name and affiliation on the attendee list.				

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event 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 or postponed, 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.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.