

How to Prepare for Pharmacovigilance Audits and Inspections

26-27 April 2017

NH Berlin Alexanderplatz, Berlin, Germany



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.

LEARNING OBJECTIVES

At the conclusion of this course, participants will 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
- 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

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

WHO WILL ATTEND

Professionals who work in:

- Pharmacovigilance/Drug safety (QPPV)
- Regulatory Affairs
- Quality & Compliance
- 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' experience in pharmacovigilance this course is at an intermediate level. Professionals with experience from the pharmacovigilance auditing area will find this course to be a refresher, and opportunity to get the most recent updates.

FACULTY

Patricia Bocciarelli

International Project Leader in
Pharmacovigilance Quality System
Marta Gersberg Conseil
France

DAY 1

08:30 REGISTRATION

09:00 SESSION 1

QUALITY SYSTEM IN PHARMACOVIGILANCE

GVP Modules I quality system and II PSMF

10:30 COFFEE BREAK

11:00 SESSION 2

AUDITS IN PHARMACOVIGILANCE

Examples of system audits including partners

12:30 LUNCH

13:30 SESSION 3

EUROPEAN AND FDA INSPECTIONS

EU GVP Module III, risk-based approach, main steps for regulatory inspections international scope (FDA, MHRA, ANSM etc.)

15:00 COFFEE BREAK

15:30 SESSION 3 CONTINUED

EUROPEAN AND FDA INSPECTIONS

Requests from inspectors, Inspection reports

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 SESSION 4

PHARMACOVIGILANCE REQUIREMENTS AND FINDINGS

PhV findings by process, trend analysis, exercise: finding detection

10:00 COFFEE BREAK

10:30 SESSION 5

RESPONDING TO THE FINDINGS AND PREPARING THE CAPA

Methodology, root cause analysis, examples of responses with exercise

12:00 LUNCH

13:00 SESSION 6

ONSITE AUDIT/INSPECTION

Preparation, organisation

14:30 COFFEE BREAK

15:00 SESSION 6 CONTINUED

ONSITE AUDIT/INSPECTION

Detailed inspection sessions, organisation, do/don't do list, coordination and examples of inspection reports, and behaviour during inspection. Exercise: audit/inspection agenda

16:30 END OF THE TRAINING COURSE

Training Course Venue

NH Berlin Alexanderplatz

Landsberger Allee 26-32

10249 Berlin, Germany

Tel: +49 30 422 61 30

Email: nhberlinalexanderplatz@nh-hotels.com

www.nh-hotels.com/hotel/nh-berlin-alexanderplatz

DIA has booked a limited number of hotel rooms at the rate of EUR 96.90 per standard single room per night including breakfast, service charges and VAT.

If you would like to make a booking, please contact the hotel directly and quote the reference "DIA":

Tel: +49 30 2238 02 33 or +800 0115 0116

Email: reservierungen@nh-hotels.com

The room rate is available until 26 March 2017 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Airport Berlin Tegel:

Travel by bus TXL until S+U Alexanderplatz Station.

Transfer to the M5 tram towards Zingster Strasse or the M6 tram towards Riesaer Strasse and exit at Klinikum im Friedrichshain Station.

The hotel is located across the street from the tram station.

Alternatively, travel by taxi for a 15-20 minute trip.

From Airport Berlin-Schönefeld:

Travel on the S9 train towards Westkreuz and exit at Alexanderplatz.

Transfer to either the M5 tram towards Zingster Strasse or the M6 tram towards Riesaer Strasse and exit at Klinikum im Friedrichshain Station.

The hotel is located across the street from the tram station.

Alternatively, travel by taxi for a 30-35 minute trip.

www.bvg.de/en



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DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 12 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 12 credits.



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REGISTRATION FORM

How to Prepare for Pharmacovigilance Audits and Inspections # 17550
26-27 April 2017 | NH Berlin Alexanderplatz | Berlin, Germany



REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 <input type="checkbox"/>	€ 1'605.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 <input type="checkbox"/>	€ 880.00 <input type="checkbox"/>

All registration fees are subject to applicable German VAT

Please enter your company's German VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

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The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. **Tel.:** +41 61 225 51 51 **Fax:** +41 61 225 51 52

Email: EMEA@DIAglobal.org **Mail:** DIA Europe, Middle East & Africa, K uchengasse 16, 4051 Basel, Switzerland

Web: www.DIAglobal.org

CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks 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

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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 office of any such substitutions as soon as possible.

PHOTOGRAPHY POLICY

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ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

Prof Dr Ms Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Fax Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

Please charge my VISA MC AMEX

Card N°

Exp. Date

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Cardholder's Name

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." Please include your name, company, Course ID # 17550 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. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on <http://www.diaglobal.org/EUTerms>

Date

Signature