

How to Prepare for Pharmacovigilance Audits and Inspections

12-13 March 2018

Adina Apartment Hotel Berlin Checkpoint Charlie, 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: Intermediate, for professionals who have fundamental understanding of Pharmacovigilance, but not necessarily experience in audits.

FACULTY

Patricia Bocciarelli

International Project Leader in
Pharmacovigilance Quality System
Marta Gersberg Conseil
France

DAY 1

08:00 REGISTRATION

08:30 SESSION 1

QUALITY SYSTEM IN PHARMACOVIGILANCE

GVP Modules I quality system and II PSMF

10:00 COFFEE BREAK

10:30 SESSION 2

AUDITS IN PHARMACOVIGILANCE

Examples of system audits including partners

12:00 LUNCH

13:00 SESSION 3

EUROPEAN AND FDA INSPECTIONS

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

14:30 COFFEE BREAK

15:00 SESSION 3 CONTINUED

EUROPEAN AND FDA INSPECTIONS

Requests from inspectors, Inspection reports

16:30 NETWORKING RECEPTION

17:30 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

| Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact EMEA@diaglobal.org.

Training Course Venue

ADINA APARTMENT HOTEL BERLIN CHECKPOINT CHARLIE

Krausenstrasse 35-36
10117 Berlin, Germany
Tel: +49 30 200 76 70
Email: berlincc@adina.eu

DIA has booked a limited number of hotel rooms at the rate of EUR 129.00 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 30 200 76 70
Email: aber@adina.eu

The room rate is available until 11 February 2018 or until the room block is sold-out, whichever comes first.



HOW TO GET THERE

The closest U-Bahn/Underground station is the line U6 "Stadtmitte". Take the exit to Friedrichstrasse and turn left in to Krausenstrasse. The hotel is located 3 blocks ahead on the right hand side.

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

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.



Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact EMEA@DIAglobal.org for a custom group rate.

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REGISTRATION FORM

How to Prepare for Pharmacovigilance Audits and Inspections # 18550
12-13 March 2018 | Adina Apartment Hotel Berlin Checkpoint Charlie | Berlin, Germany



REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the 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:

I do not want complimentary membership

The DIA 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, Küchengasse 16, 4051 Basel, Switzerland

Web: www.DIAglobal.org

TERMS AND CONDITIONS

CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA 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 AND VIDEO 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 in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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

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 #18550 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.**

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