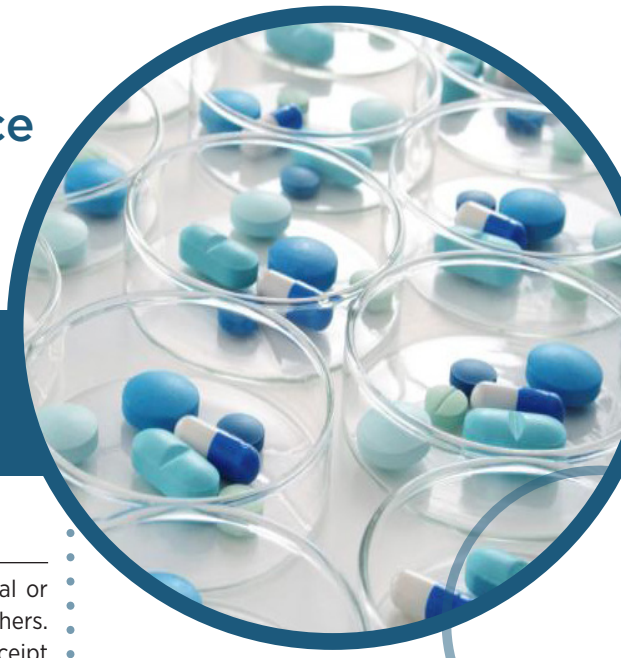
DIA Training Course on

How to Prepare for Pharmacovigilance Audits and Inspections



19-20 April 2016
Mercure Paris La Dèfense Grande Arche, Paris, France

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 withfeedback 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.

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

INSTRUCTOR

Patricia Bocciarelli
International Project Leader in Pharmacovigilance Quality System
Marta Gersberg Conseil
France

CONTINUING EDUCATION

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 9 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9 credits.

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

DEVELOP. INNOVATE. ADVANCE.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

DAY 1

12:30 REGISTRATION

13:00 SESSION 1

AUDITS IN PHARMACOVIGILANCE

Quality system, methodology, risk-based approach, the PSMF, examples of system audits

15:00 COFFEE BREAK

15:30 SESSION 2

EUROPEAN AND FDA INSPECTIONS

New Legislation, risk-based approach, main steps for regulatory inspections

17:00 DRINKS RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 SESSION 3

PHARMACOVIGILANCE REQUIREMENTS AND FINDINGS

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

10:00 COFFEE BREAK

10:30 SESSION 4

RESPONDING TO THE FINDINGS AND PREPARING THE CAPA

Methodology, root cause analysis, examples of responses with exercises

12:00 LUNCH BREAK

13:00 SESSION 5

ONSITE AUDIT/INSPECTION

Preparation, organisation

14:30 COFFEE BREAK

15:00 SESSION 4

ONSITE AUDIT/INSPECTION (Cont.)

Exercise: inspection agenda, detailed inspection sessions, examples of inspection reports, and behaviour during inspection

16:30 END OF THE TRAINING COURSE

Training Course Venue

The training course will take place at:

Paris La Défense Grande Arche
17/20 Esplanade Ch. de Gaulle - Rue des Trois Fontanot
92000 Nanterre/Paris, France
Tel: +33 8 2580 5959
Fax: +33 1 4725 4624
Email: H1982@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 180.00 per standard room per night including breakfast and VAT, excl. City-Tax.

If you would like to make a booking, please fill in the booking form available on the DIA website and send it per email to H1982@accor.com with a reference "DIA".

The room rate is available until 18 March 2016 or until the room block is sold-out, whichever comes first.

About DIA

In 1964, 30 visionary pharmaceutical research professionals came together with a noble mission – to increase communication and collaboration in drug development in order to improve safety and advance therapeutic success.

Over the next 50 years, DIA grew to a global not for profit organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: to improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

REGISTRATION FORM

How to Prepare for Pharmacovigilance Audits and Inspections # 16550
19-20 April 2016 | Mercure Paris La Défense Grande Arche | Paris, France

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REGISTRATION FEES

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

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'240.00 ❑	€ 1'395.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 ❑	€ 775.00 ❑

All registration fees are subject to applicable French VAT

Please enter your company's French 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 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, Küchengasse 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

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

email (Required for confirmation) 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 # 16550 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