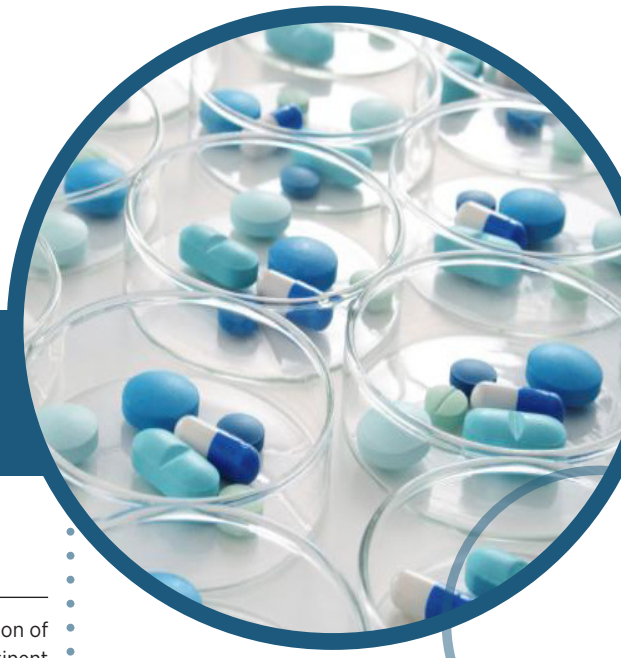
DIA Training Course on

Pre-Marketing Clinical Safety



Course #15539
18-19 May 2015
Holiday Inn – Kensington Forum, London, UK

OVERVIEW

DIA is presenting an intensive course for professionals involved in management of safety information of clinical trials in the EU. Participants will be guided through all the regulations and guidelines pertinent to pre-marketing safety in the EU. The course offers an overview of all the current major methodological approaches and hands-on solutions for day-to-day challenges. Attendees will learn how to produce Development Safety Update Reports (DSURs), and how to bridge a Development Risk Management Plan, EU-Risk Management Plan (EU-RMP) and Risk Evaluation and Mitigation Strategies (REMS) to be ready for a marketing authorisation application.

LEARNING OBJECTIVES

At the conclusion of this training course participants will be able to:

- Understand key concepts of drug safety and pharmacovigilance and their application to clinical development
- Know how to comply with European regulations for clinical safety, including production, management and submission of an Adverse Event (AE), Serious Adverse Event (SAE), and Suspected Unexpected Serious Adverse Reactions (SUSARs)
- Prepare DSURs
- Understand regulatory reporting requirements for products already marketed while their development continues
- Understand risk assessment methodology and its use in the development risk management plans, forming basis for EU-RMP and REMS

WHO WILL ATTEND

- Drug safety managers, specialists and directors involved in clinical trials
- Clinical trial monitors and managers wishing to acquire deeper knowledge of drug safety science and regulations
- Pharmacovigilance professionals involved in pre-marketing safety

KEY TOPICS

- Management of adverse events
- Unblinding strategies
- SUSARs reporting
- How to inform of ethics committees
- Development safety update reports
- EudraVigilance CT module
- Risk assessment in clinical trials
- Safety risk management

FACULTY

Jan Petracek
CEO, European PharmInvent Services, Czech Republic
Former Head of Risk Management, European Medicines Agency, EU

Michael Forstner
Head Pharmacovigilance Europe
Boehringer-Ingelheim RCV GmbH&Co KG, Austria

CONTINUING EDUCATION

DIA meetings and training courses are generally approved by the Commission for Professional Development (ZCPD) 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.

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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.

DIAHome.org

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

DAY 1

08:30 — **REGISTRATION**

08:45 — **INTRODUCTION AND WELCOME**

9:00 — **SESSION 1**

FUNDAMENTALS

- The Concepts, Principles and Terminology
- CIOMS, ICH, ISO, Investigators Brochure, Informed Consent
- European Clinical Trial Directive
- European Guidelines (Volume 10 and 9A)
- Examples of National Implementation

10:00 — **SESSION 2**

PLAYERS

- Sponsor & Investigator Responsibilities
- Ethics Committees
- The National Authorities
- EMA, EU Commission, Expert working groups, GCP inspections

10:30 — **COFFEE BREAK**

11:00 — **SESSION 3**

MANAGEMENT OF ADVERSE EVENTS

- Case Capture, CRFs vs. EDC
- Organisation of a PV Unit Case Flow & EDC systems
- Assessing and coding AEs
- Good PV Practices
- Good Documentation Practices, Medical Records & Archiving
- Drug Interactions & Polypharmacy

13:00 — **LUNCH**

14:00 — **SESSION 4**

EXPEDITED REPORTING

- Expedited Reporting Rules
- EudraVigilance CT module
- Causality assessment
- SAE and SUSARs, unbliding rules

15:30 — **COFFEE BREAK**

16:00 — **SESSION 5**

AGGREGATE REPORTING

- Development Safety Update Report (ICH E2F)
- Regional - EU Annual Safety Report and US IND Annual Report
- Clinical Study Reports, ICH E3 & Lab Data

17:30 — **DRINKS RECEPTION**

18:30 — **END OF DAY ONE**

DAY 2

08:30 — **SESSION 6**

ORGANISATION AND OVERSIGHT

- CROs & Drug Safety
- Contractual Agreements
- Data Safety Monitoring Boards
- Quality & Key Performance Indicators
- Training
- Data Privacy
- Audits & Inspections
- Insurance
- Ethics & Conflicts of Interest

10:00 — **COFFEE BREAK**

10:30 — **SESSION 7**

MATHEMATICS OF DRUG SAFETY AND SAFETY RISK MANAGEMENT

- Mathematics of Drug Safety
- Risk Assessment in Clinical Trial
- Development Risk Management Plan
- Links to EU-RMP, REMS, DSUR and PSUR

12:00 — **LUNCH**

13:00 — **SESSION 8**

EXAMPLES AND PRACTICAL EXERCISES

- ICSR causality assessment
- SUSAR reporting
- DSUR preparation for a global trial involving EU, US and India.

14:50 — **COURSE ASSESSMENT**

15:20 — **END OF TRAINING COURSE**

COURSE VENUE

Holiday Inn London Kensington Forum

97 Cromwell Road

London, SW7 4DN

Tel: +44 871 942 9094

http://www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 17 to 20 May 2015 at the rate of GBP 168.00 per single room per night including Full English Breakfast, taxes and service fee. In order to book a hotel room, please call the hotel directly and quote the booking reference "VGO".

The room rate is available until **5 April 2015** or until the room block is sold-out, whichever comes first. Cancellations received after 5 April 2015 will be subject to cancellation fee of 100% of the booking value.

REGISTRATION FORM

Pre-Marketing Clinical Safety, # 15539, 18-19 May 2015, London, UK

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FEES

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

FEES	MEMBER*	NON-MEMBER*
INDUSTRY	€ 1'420.00 ❑	€ 1'580.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 710.00 ❑	€ 870.00 ❑
Join DIA now to qualify for the member rate	€ 130.00 ❑	

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

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit **www.DIAHome.org** and click on Membership for more details.

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

The DIA EMEA Contact Center 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: diaeurope@diaeurope.org Mail: DIA EMEA, Küchengasse 16, 4051 Basel, Switzerland Web: www.diahome.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
- Tutorial cancellation € 50.00

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)

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 # 15539 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.diahome.org/EUTerms

Date	Signature

EUROPE, MIDDLE EAST & AFRICA

2015 TRAINING COURSES

DIA DEVELOP INNOVATE ADVANCE

Chemistry, Manufacturing and Controls

21-23 SEP VIENNA, AUSTRIA | #15543
Quality by Design - New concepts for chemical and biotech product development and optimisation

Participants from pharmaceutical, biotech and generic industry as well as regulators will learn how to use QRM, Process Characterisation, DoE, Development of a Design Space and Control Strategy, as well as the tools of Knowledge Management (KM).

26 APR DAKAR, SENEGAL | #15553
Global CTD Dossier – Regulatory aspects and focus on quality documentation including concepts of Quality by Design

This course provides a comprehensive description on the Common Technical Dossier structure – completely updated to reflect the latest changes in pharmaceutical regulatory affairs.

Clinical Research

10-12 JUN PARIS, FRANCE | #15557
Essentials of Clinical Study Management

After successful completion of the training course, participants will be able to plan, execute and manage a clinical study from protocol to final report.

16-18 NOV LONDON, UK | #15555
Clinical Project Management – Part II

This is the second part of the 2-part course on Clinical Project Management, concentrating on specific concepts such as project quality risk management.

16-18 SEP LONDON, UK | #15542
Clinical Project Management – Part I

This course provides a comprehensive foundation in clinical project management. Using the Project Management Body of Knowledge (PMBOK®) as a guide, participants will be taught how to apply project management strategies, tools and techniques to their clinical trial projects.

14-16 OCT LONDON, UK | #15531
Practical GCP Compliance Auditing of Trials and Systems

This course provides practical training for industry auditors and regulatory authority inspectors, who are faced with the task of auditing clinical trials and related systems. It will also be of interest to those with managerial responsibilities.

15-16 OCT LONDON, UK | #15532
Clinical Statistics for Non-Statisticians

This course is an introduction of basic statistical concepts fundamental to clinical research, for professionals who have regular exposure to statistics.

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with

IN-HOUSE TRAINING

All DIA Training Courses can be held on your premises and tailored to your needs.

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Regulatory Affairs

10-11 MAR HAMBURG, GERMANY | #15541
26-27 NOV VIENNA, AUSTRIA | #15556
Essentials of European Regulatory Affairs

This is the must-attend training course for anyone needing to learn the essentials of European Regulatory Affairs.

16-18 NOV LONDON, UK | #15554
US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US

This course is designed for persons with a background in pre-clinical research, clinical research, quality assurance or academia, who need knowledge of the US regulatory processes.

FEB DUBAI, UNITED ARAB EMIRATES #15562
Building the eCTD - Practical Approaches to compiling Electronic Submissions

Participants will learn about the Electronic Common Technical Document (eCTD), its components and history, preparing submission ready documents, and how to change your business processes in preparation for moving towards electronic submissions.

17-18 SEP LONDON, UK | #15552
Paediatric Investigation Plans (PIP)

This course will provide a full introduction to PIPs and the EU Paediatric Regulation.

21-23 SEP VIENNA, AUSTRIA | #15536
Medical Devices: Regulation and lifecycle management

All you need to know about medical devices, if you are not working with devices on a daily basis or your need an overview.

14-15 OCT LONDON, UK | #15546
How to Prepare for your Meeting with Health Authorities

This course covers Health Authority (HA) meetings and other interactions in the EU and the US. You will learn by performing role plays yourself and by many case studies.

25-27 NOV VIENNA, AUSTRIA | #15545
Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe - Development and Regulatory Framework in Europe

Participants will learn about the legislative and regulatory framework for biopharmaceuticals in Europe and the roles of the European Medicines Agency and National Competent Authorities in market access.

OCT DUBAI, UNITED ARAB EMIRATES #15561
Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview

This is a complete comprehensive in-depth training on European regulatory affairs, exploring all aspects of medicinal product lifecycle management.

NEXT OCCURANCE TO BE ANNOUNCED
Approval of Generic Medicines in the EU. Focus on CMC requirements and bioequivalence

The overall requirements for the approval of generics will be detailed including problems in relation to generic substitution and falsified medicines.

*See course programme for details

Safety and Pharmacovigilance

Combo Pricing*

28-29 APR BASEL, SWITZERLAND | #15550
How to Prepare for Pharmacovigilance Audits and Inspections

The course will teach you how to prepare for an inspection from the announcement (or of the arrival of the inspectors at your doorstep) to the conclusion.

27-28 APR BASEL, SWITZERLAND | #15534
Signal Management in Pharmacovigilance

The course will teach basic concepts of signal detection and signal management and how to apply them within the participants' functions.

10-11 MAR HAMBURG, GERMANY | #15533
Benefit/Risk Management

This intensive course explores current opportunities made possible by the new legislation, advances in information technology and a new scientific methodology to enhance and modernise the approaches in the product lifecycle management.

9-13 FEB LONDON, UK | #15548
Excellence in Pharmacovigilance: Clinical trials and post-marketing

In just five days, you will gain a firm grounding in key aspects of safety and pharmacovigilance from a European and global standpoint.

12-13 FEB ALGIERS, ALGERIA | #15570
26 APR DAKAR, SENEGAL | #15559
ICH Endorsed Pharmacovigilance

Participants will gain solid knowledge and a clear understanding of international approaches to drug safety pharmacovigilance, as well as the best practices for successful local and global regulatory applications.

Combo Pricing*

10-11 JUN PARIS, FRANCE | #15540
Medical Approach in Diagnosis and Management of ADRs

How to use medical knowledge in the diagnosis and management of selected Adverse Drug Reactions (ADRs).

11-12 JUN PARIS, FRANCE | #15544
Diagnosis and Management of Drug-Induced Liver Injury (DILI)

This course will provide tools, explanations, examples and several exercises for a better understanding of DILI and how best to apply that knowledge in day to day work.

21-22 SEP BERLIN, GERMANY | #15535
Post-Authorisation Safety Studies (PASS)

This course delivers insight in (pharmaco-)epidemiological methodology for non-interventional studies, and the concept of multi-departmental collaboration for the development and conduct of a PASS.

YEAR-ROUND
EMA HEADQUARTERS, LONDON
AND SELECTED EUROPEAN CITIES

EudraVigilance Courses

EudraVigilance — Electronic Reporting of ICSRs in the EEA

eXtended EudraVigilance Medicinal Product Dictionary

Introduction to Pharmacovigilance and Rules for Expedited Reporting of Individual Case Safety Reports (ICSRs) in Europe

Discover new opportunities at **diahome.org.** Call DIA offices at +41 61 225 51 51 or diaeurope@diaeurope.org