ICH Endorsed Pharmacovigilance Training Course

Course #13568
22-23 September 2013
Barr Al Jissah Hotel, Muscat, Sultanate of Oman

Programme Committee

Europe

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

Kingdom of Saudi Arabia, Saudi Food and Drug Authority

Prof. Saleh A Bawazir
Vice President for Drug Affairs

Dr Adel AlHarf
Director of National Pharmacovigilance Center

Dr Ghazi S Saeed
Executive Director of Pharmacovigilance and Crisis Management

Sultanate of Oman, Ministry of Health

Dr Sawsan Ahmed Jaffar
Director General of Pharmaceutical Affairs & Drug Control

Dr Shirly S. Varughese
Pharmacologist

Faculty

Kingdom of Saudi Arabia, Saudi Food and Drug Authority

Ph. Khaled W Alshahwan
Director of Clinical Trial Directorate

Ph. Ali Yahya Alshahrani
Adverse Reaction Assessor

Ph. Mubarak Saeed Alshaharani
Drug Safety Evaluator

Ph. Yaser Suaod Alrdayaan
Pharmacist

Ph. Naser Abdullah Aljaser
Senior Pharmacist

Sultanate of Oman, Ministry of Health

Ph. Mohammed Hamdan Al Rubaie
Director, Department of Drug Control

Ph. Ahmed Al Harbi
Clinical Pharmacist

Ph. Madiha Al Maskari
Section Head, International Communication & ADR Centre

Ph. Hussain Al Ramimmy
Section Head, Inspection, Pharmacy Department

Overview

This training course focuses on ICH international standards related to pharmacovigilance (ICH E2 series). It covers both pre- and post-authorisation pharmacovigilance standards and practical implementation of the ICH guidelines in the international environment. The course includes case studies and examples of challenges and practical solutions. The course is prepared and taught by experienced pharmacovigilance experts. 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.

Key Topics

- ICH E2A Pre-marketing safety
- ICH E2D Definitions and standards for expedited reporting (post–approval)
- ICH E2B (both pre-and post-authorisation) Data elements for electronic submission
- ICH E2F Development Safety Update Report
- ICH E2C(R2) Periodic Benefit Risk Evaluation Report (PBRER) Guideline
- ICH E2E Pharmacovigilance planning

Who Will Attend

Professionals with background in the following areas:
- Clinical Research
- Clinical Safety/Pharmacovigilance
- Information Technology/Document Management
- Public Policy/Law/Compliance
- Regulatory Affairs
- Research & Development
- Risk Management

Learning Objectives

At the conclusion of this course, participants should be able to:
- Understand the international history, the principles and regulatory framework for pre- and post-approval clinical safety/pharmacovigilance
- Recognise the need for international safety surveillance and understand the regulatory requirements
- Understand the basic definitions of terms, scope of work, and purpose of pharmacovigilance used in day-to-day work
- Demonstrate an awareness of risk management and optimal risk minimisation methods

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.

This course has limited capacity. Register early.

ICH harmonisation for better health

DIA®
www.diahome.org

DAY 1

08:00 REGISTRATION

08:45 **Opening remarks**

09:00 **Session 1**
INTRODUCTION OF ICH PHARMACOVIGILANCE GUIDELINES

09:30 **Session 2**
ICH E2A PRE-MARKETING SAFETY
Local perspective

10:50 COFFEE BREAK

11:20 **Session 3**
ICH E2D DEFINITIONS & STANDARDS FOR EXPEDITED REPORTING (POST-APPROVAL)
Local perspective

12:40 LUNCH

13:40 **Session 4**
ICH E2B (BOTH PRE- AND POST-AUTHORISATION) DATA ELEMENTS FOR ELECTRONIC SUBMISSION
Local perspective

15:30 COFFEE BREAK

16:00 **Session 5**
ICH E2F DEVELOPMENT SAFETY UPDATE REPORT
Local perspective

17:30 END OF DAY ONE

DAY 2

09:00 **Session 6**
ICH E2C (R2) PERIODIC BENEFIT RISK EVALUATION REPORT (PBRER) GUIDELINE
Local perspective

10:30 COFFEE BREAK

11:00 **Session 6 continued**
ICH E2C (R2) PERIODIC BENEFIT RISK EVALUATION REPORT (PBRER) GUIDELINE
Local perspective

11:45 **Session 7**
ICH E2E PHARMACOVIGILANCE PLANNING
Local perspective

13:15 LUNCH

14:15 **Session 8**
Case studies of practical exercises related to the ICH implementation in EU and US
Case studies and discussion on local aspects

15:45 END OF TRAINING COURSE

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.

HOTEL INFORMATION

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

Barr Al Jissah Hotel
P.O. Box 644 - 113 Muscat
Sultanate of Oman

Tel.: 00968 2477 6666 - Fax: 00968 2477 6677
Website: **http://www.shangri-la.com/muscat/barraljissahresort/**

at the rate of:
OMR 70.00 Al Bandar Deluxe Room single occupancy and OMR 80.00 double occupancy inclusive of breakfast buffet, exclusive of service charge and taxes of 17%.

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

Important: The room rate is available until 21 August 2013 or until the group block is sold-out, whichever comes first.

Cancellation: No show charges to apply without a notification from the hotel. Bookings cancelled after 22 July 2013 will be charged 100% cancellation fee.

DIA EUROPE TRAINING PROGRAMME 2013-2014

Chemistry, Manufacturing and Controls (CMC) / Quality

- **Global CTD Dossier – Regulatory aspects and focus on quality documentation including concepts of Quality by Design**
  1-3 December 2013 | Dubai, United Arab Emirates | ID 13562
- **Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators**
  11-13 September 2013 | Vienna, Austria | ID 13559

Clinical Research

- **Advanced GCP Study Monitoring**
  Next recurrence of this course to be announced
- **Clinical Project Management – Part I**
  18-20 September 2013 | Basel, Switzerland | ID 13572
- **Clinical Project Management – Part II**
  25-27 November 2013 | Zurich, Switzerland | ID 13501
- **Clinical Statistics for Non-Statisticians**
  24-25 October 2013 | London, United Kingdom | ID 13551
- **Essentials of Clinical Study Management**
  20-22 November 2013 | Paris, France | ID 13554
- **Practical GCP Compliance Auditing of Trials and Systems**
  23-25 October 2013 | London, United Kingdom | ID 13548

Non-Clinical Safety Sciences

- **Non-Clinical Safety Sciences and Their Regulatory Aspects**
  February 2014 | Lisbon, Portugal

Regulatory Affairs

- **Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe**
  18-20 September 2013 | Basel, Switzerland | ID 13546
- **European Regulatory Affairs: In-depth review of current registration procedures in the European Union**
  21-22 November 2013 | Paris, France | ID 13553
- **Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices**
  Next recurrence of this course to be announced
- **Health Authority Interactions – Preparation, consultation and implementation**
  15-16 October 2013 | Vienna, Austria | ID 13575
- **Health Technology Assessment (HTA)**
  26-27 November 2013 | Zurich, Switzerland | ID 13561
- **Paediatric Investigation Plans (PIP)**
  November 2013 | Location to be confirmed
- **The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)**
  2-4 October 2013 | Basel, Switzerland | ID 13532
- **US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US**
  6-8 November 2013 | Paris, France | ID 13552

Safety and Pharmacovigilance

- **Benefit/Risk Management**
  26-27 September 2013 | Prague, Czech Republic | ID 13524
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  19-20 September 2013 | Paris, France | ID 13563
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  7–8 November 2013 | Paris, France | ID 13556
- **ICH Endorsed Pharmacovigilance**
  22-23 September 2013 | Muscat, Sultanate of Oman | ID 13568
  28-29 November 2013 | Zagreb, Croatia | ID 13569
- **Pre-Marketing Clinical Safety**
  Next recurrence of this course to be announced
- **Signal Management in Pharmacovigilance**
  6–7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses

- **EudraVigilance Information Day**
  22 October 2013 | London, United Kingdom | ID 13530
- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  18-22 November 2013 | London, United Kingdom | ID 13522
- **IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day**
  10 December 2013 | London, United Kingdom | ID 13531
- **EudraVigilance courses:**
  - EudraVigilance – Electronic reporting of ICSRs in the EEA
  - eXtended EudraVigilance Medicinal Product Dictionary
  - Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses.

DIA Europe Tailored Training

DIA Europe Tailored Training is a highly flexible, efficient and cost-effective way to get the maximum return on your training investment. Schedule your training course when it suits you best, at the venue of your choice. You can even adapt the content to include areas specific to your environment, and to match the level of expertise of the audience.

DIA Tailored Training is available to both public and private institutions and is delivered by instructors with no conflict of interest.

The DIA Tailored Training programmes in Europe make the most of a selection of world-class expert faculty who are experienced professionals in the pharmaceutical and related industries.

Contact DIA Europe to discuss your organisation's requirements.

For more information and a complete listing of all DIA conferences and training courses, please visit:
www.diahome.org > click on Meetings & Training
Call DIA Europe on +41 61 225 51 51 or email: diaeurope@diaeurope.org

DIA®
www.diahome.org

REGISTRATION FORM

ICH Endorsed Pharmacovigilance Training Course

22-23 September 2013 | Barr Al Jissah Hotel, Muscat, Sultanate of Oman

DIA www.diahome.org

ID# 13568

FEES

	Member	Non-Member
Industry	€ 1'365.00 ❑	€ 1'480.00 ❑
Academia/Charitable/Non-profit (Full-time)	€ 500.00 ❑	€ 615.00 ❑
Government	€ 400.00 ❑	€ 515.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

If you register for both The *10th Middle East Regulatory Conference (MERC) 2013* and The *ICH Endorsed Pharmacovigilance Training Course*, you will receive 50% off the ICH Endorsed Pharmacovigilance Training Course fee – this offer is only available by emailing diaeurope@diaeurope.org.

TOTAL AMOUNT DUE: _____

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

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.

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

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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 # 13568 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.**

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

Date	Signature

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.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Postfach, 4002 Basel, Switzerland

© DIA 2013