DIA Training Course on

Practical GCP Compliance Auditing of Trials and Systems

Course #13548
23-25 October 2013
Holiday Inn London – Kensington Forum, London, UK

Faculty

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Belgium

European Medicines Agency Representatives Invited

MHRA Representative Invited

This course has limited capacity. Register early.

Overview

This GCP auditing course is designed to provide practical training resulting in a harmonised, common audit methodology in Europe. The ICH GCP guideline implemented in the EU, Japan and the USA is being widely incorporated into guidelines worldwide. Systems audits, previously seen as "advanced auditing", have become a basic task of many audit groups and are an essential element of inspections in Europe.

The course material is regularly updated with the objective of experience sharing and a common professional approach in order to pave the way for mutual recognition and acceptance, reducing costs and stimulating efficiency, allowing faster medicinal product development to the benefit of the patients and health care.

Key Topics

- Regulatory framework EU and ICH
- Quality management, defining quality, risk-based approach to audit and inspection
- Trial audit in practice
- System audits
- Communication of audit findings
- Inspections by European and other authorities

Who Will Attend

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

Learning Objectives

At the conclusion of this course, participants should be able to:
- Apply common audit methodology principles to clinical trials in Europe and other countries
- Compare trial specific and system audits
- Formulate audit findings in clear and precise language
- Discuss requirements for inspections

Continuing Education

DIA meetings and trainings are generally approved by the Commission for Professional Development (CPD) 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 and certificates are available.

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WEDNESDAY | 23 OCTOBER 2013

07:30 **REGISTRATION**

08:30 **WELCOME**
Introduction of faculty; background of participants; course procedures and objectives; participants' expectations

08:50 **Session 1**

GCP REGULATORY FRAMEWORK IN EUROPE AND IN THE ICH REGIONS AND THE IMPLEMENTATION OF QUALITY SYSTEMS

- Regulatory framework
- How do you define quality? Quality management system principles
- Risk-based approach to audit and inspection

Discussion

10:00 **COFFEE BREAK**

10:30 **Session 1 continued**

- Dealing with infringement - poor practice/questionable conduct/ fraud

Discussion

Breakout session:
Audits – defining quality, priority and risk-based approach

Feedback from breakout session

12:30 **LUNCH**

13:45 **Session 2**

AUDIT METHODOLOGY AND PLANNING

- General audit methodology and planning: ISO 19011:2002
- Trial specific audit versus system audit. Audit programme(s)
- Inspection findings
- Audit reports

Discussion

15:30 **COFFEE BREAK**

16:00 **Session 2 continued**

- Cultural challenges of auditing
- Non-technical aspects of audits and inspections

Discussion

Breakout session:
Audit methodology and planning; dealing with difficult situations

Feedback from breakout session

18:00 **DRINKS RECEPTION**

19:00 **END OF DAY ONE**

THURSDAY | 24 OCTOBER 2013

08:30 **Session 3**

THE TRIAL AUDIT IN PRACTICE – INVESTIGATOR SITE

- Trial master file
- Audit of consent form and the informed consent process
- Source documentation and data verification

Discussion

10:00 **COFFEE BREAK**

10:30 **Session 3 continued**

- Monitoring

Discussion

Breakout session:
Investigator site audit

Feedback from breakout session

12:30 **LUNCH**

13:45 **Session 4**

USE OF COMPUTERS IN CLINICAL TRIALS

- Validation, e-source, e-CRF, IVRS
- Audit of computer systems

Discussion

15:00 **Session 5**

DATA MANAGEMENT AND ANALYSIS

- Data management

Discussion

15:30 **COFFEE BREAK**

16:00 **Session 5 continued**

- Statistical analysis and reporting

Discussion

Breakout session:
Use of computers and data analysis

Feedback from breakout session

18:00 **END OF DAY TWO**

FRIDAY | 25 OCTOBER 2013

08:30 Session 6

SYSTEMS AUDITS
- Drug safety audit
- Laboratory
- Phase I sites

Discussion

10:00 COFFEE BREAK

10:30 Session 6 continued
- Investigational medicinal product

Discussion

Breakout session:
System audit

Feedback from breakout session

12:30 LUNCH

13:45 Session 7

INSPECTIONS BY EUROPEAN AND THIRD COUNTRY AUTHORITIES
- Inspection by European authorities
- Inspection by US FDA and other authorities

Discussion

15:00 FINAL DISCUSSION AND COURSE EVALUATION

15:30 END OF TRAINING COURSE

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

HOTEL INFORMATION

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

Holiday Inn London – Kensington Forum
97 Cromwell Road
SW7 4DN London
United Kingdom

Tel.: +44 207 341 8000
Website: http://www.hikensingtonforumhotel.co.uk/

at the rate of:
GBP 162.00 per room/night inclusive of breakfast and VAT.

In order to make your reservation, please contact the hotel directly at +44 207 341 8000 and quote the booking reference: DDB.

IMPORTANT: The room rate is available until 16 September 2013 or until the group block is sold-out, whichever comes first.

REGISTRATION FORM

DIA Training Course on Practical GCP Compliance Auditing of Trials and Systems
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ID #13548

FEES

		Member	Non-Member
Industry	€	1'785.00 ❑	€ 1'900.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€	893.00 ❑	€ 1'008.00 ❑
Join DIA now to qualify for the member rate	€	115.00 ❑	

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

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

TOTAL AMOUNT DUE: _____

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

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 #13548 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.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

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:

- Full Meeting Cancellation: 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 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.

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