

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

Course #14531
22-24 October 2014
Holiday Inn - Kensington Forum, London, UK



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**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. 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 system and vendor 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
- Conduct trial specific and system audits
- Formulate audit findings in clear and precise language
- Discuss requirements for 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.

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.

PharmaTrain recognised



WEDNESDAY | 22 OCTOBER 2014

07:30 REGISTRATION

08:30 WELCOME

Introduction of faculty; background of participants; course procedures and objectives; participants' expectations

09:00 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
- Trial specific audit versus system audit. Defining an audit programme

Discussion

10:10 COFFEE BREAK

10:40 Session 1 continued

- Risk-based approach to audit and inspection and audit planning

Discussion

Breakout session:

Defining quality and risk based approach to audit planning

Feedback from breakout session

12:20 LUNCH

13:20 Session 2

AUDIT METHODOLOGY AND REPORTING

- General audit methodology and planning: ISO 19011:2002
- Non-technical aspects of audits and inspections: cultural awareness
- Audit reports

Discussion

14:45 COFFEE BREAK

15:15 Session 2 continued

Breakout session:

Audit methodology and reporting.

Feedback from breakout session

- Inspection findings

Discussion

17:15 COURSE ASSESSMENT

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

THURSDAY | 23 OCTOBER 2014

08:30 Session 3

THE TRIAL AUDIT IN PRACTICE - INVESTIGATOR SITE

- Trial master file and e-TMF
- 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

12:00 LUNCH

13:00 Session 4

COMPUTERS SYSTEMS AND DATA INTEGRITY

- Overview of data integrity audit
- Computer systems and standards
- Audit of computer systems
- Interactive presentation with short questions to the audience
- Data integrity from data collection to archiving

Discussion

14:50 COFFEE BREAK

15:20 Session 5

SYSTEMS AUDITS

- Drug safety audit
- Investigational medicinal product (IMP audit)

Discussion

Breakout session:

Systems audits: Safety and IMP

Feedback from breakout session

17:15 COURSE ASSESSMENT

17:30 END OF DAY TWO

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.

FRIDAY | 24 OCTOBER 2014

08:30 Session 6

VENDOR AUDITS

- Vendors audit and quality oversight
- Laboratory audit
- Phase I sites audit

Discussion

10:00 COFFEE BREAK

10:30 Session 6 continued

Breakout session:

Vendor audits

Feedback from breakout session

12:00 COURSE ASSESSMENT

12:15 LUNCH

13:15 Session 7

INSPECTIONS BY EUROPEAN AND THIRD COUNTRY AUTHORITIES

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

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 165.00 per room/night inclusive of breakfast and VAT.

In order to make your reservation, please contact the hotel directly at + 44 (0) 207 341 3355 and quote the booking reference ZNK.

IMPORTANT: The room rate is available until 22 September 2014 or until the group block is sold-out, whichever comes first.

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 headquartered 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.

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

DIA Mission

DIA fosters innovation to improve health and well-being worldwide by:

- Providing invaluable forums to exchange vital information and discuss current issues related to health products, technologies, and services;
- Delivering customized learning experiences;
- Building, maintaining, and facilitating trusted relationships with and among individuals and organisations that drive and share DIA values and mandates; and
- Offering a multidisciplinary neutral environment, respected globally for integrity and relevancy.

DIA Vision

DIA is the global forum for knowledge exchange in the pharmaceutical sector that fosters innovation to raise the level of health and well-being worldwide



REGISTRATION FORM

DIA Training Course on Practical GCP Compliance Auditing of Trials and Systems
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FEES

	Member	Non-Member
Industry	€ 1'840.00 <input type="checkbox"/>	€ 1'970.00 <input type="checkbox"/>
Academia/Charitable/Government/Non-profit (Full-time)	€ 920.00 <input type="checkbox"/>	€ 1'050.00 <input type="checkbox"/>
Join DIA now to qualify for the member rate	€ 130.00 <input type="checkbox"/>	

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 availability – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

TOTAL AMOUNT DUE: _____

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 # 14531 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.

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