DIA Practical GCP Compliance Auditing of Trials and Systems Training Course

Course #12568
17-19 October 2012
NH Harrington Hall, London, United Kingdom

FACULTY

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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 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 | 17 OCTOBER 2012

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 | 18 OCTOBER 2012

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 | 19 OCTOBER 2012

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**

HOTEL INFORMATION

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

NH Harrington Hall
5-25 Harrington Gardens
South Kensington
London SW7 4JW
United Kingdom

Tel.: +44 (0) 207 396 9696
Fax: +44 (0) 207 396 9090
Email: nhharringtonhall@nh-hotels.com

at the special rate of 170.00 GBP per room inclusive of breakfast and exclusive of VAT.

To make your reservation please:
Email: bookings@nh-hotels.com
Tel.: 0870 735 0358

Please quote the booking reference: 153777172

Important: Please complete your reservation by 16 September 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

REGISTRATION FORM

DIA Practical GCP Compliance Auditing of Trials and Systems Training Course
17-19 October 2012 | NH Harrington Hall, London, United Kingdom

ID # 12568

DIA www.diahome.org

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

CATEGORY	Member FEE	TOTAL	Non-Member (with optional membership) FEE	Membership	TOTAL	Non-Member (without optional membership) FEE	TOTAL
Industry	€ 1'785.00	**€ 1'785.00** ❑	€ 1'785.00	€ 115.00	**€ 1'900.00** ❑	€ 1'900.00	**€ 1'900.00** ❑
Government/Academia (Full-Time)	€ 893.00	**€ 893.00** ❑	€ 893.00	€ 115.00	**€ 1'008.00** ❑	€ 1'008.00	**€ 1'008.00** ❑

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

__ Advertising & Promotion
__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Eff ectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/ Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Aff airs
__ Research & Development
__ Statistics
__ Strategic Planning
__ IT/Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ VISA ❑MC ❑ AMEX

Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ Cheques should be made payable to: DIA and mailed together with a copy of the registration form to facilitate identification to: DIA, Kuechengasse 16, Postfach, 4002 Basel, Switzerland

❑ 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." including your name, company, Meeting ID# 12568 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.

Persons under 18 are not allowed to attend DIA meetings.

Please also complete the following:
I have no/or very limited GCP experience ❑
I have no/or very limited experience with auditing experience ❑
I have worked with GCP for _____ years
I have _____ years of auditing

CANCELLATION POLICY **Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date**

Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00
Regretfully, if you do not cancel five working days prior to the course 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.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org | **Fax** +41 61 225 51 52 | **Email** diaeurope@diaeurope.org | **Mail** DIA European Office, Postfach, 4002 Basel, Switzerland