Practical GCP Compliance Auditing of Trials & Systems

Course #10546
October 6-8, 2010
Park Inn London Russell Square, London, UK

Course Faculty

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Rick Walsh
Global Clinical Compliance Lead, Respiratory and Inflammation, AstraZeneca, United Kingdom

This course has limited capacity. Register early.

Course 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.

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.

Key Topics

- Regulatory Framework EU and ICH and Quality Management
- Trial audit in practice
- System audits
- Communication of audit findings
- Inspections by European and other authorities

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

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WEDNESDAY | OCTOBER 6, 2010

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
- Quality Management System Principles

HOW DO YOU DEFINE QUALITY?

- Defining quality

Discussion

10:00 **COFFEE BREAK**

10:30 **Session 1 continued**

- Risk based approach to audit and inspection
- Dealing with Infringement - Poor practice/Questionable Conduct/Fraud

Discussion

Breakout session
- Topic: 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)
- Formulation of findings

Discussion

15:30 **COFFEE BREAK**

16:00 **Session 2 continued**

- Cultural Challenges and Non-technical Aspects of Audits and Inspections

Discussion

Breakout session
- Topic: Audit methodology and planning. Dealing with difficult situations

Feedback from breakout session

18:00 **END OF DAY ONE**

19:00 **RECEPTION**

19:30 **DINNER**

THURSDAY | OCTOBER 7, 2010

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
- Topic: 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 system

15:00 **Session 5**
DATA MANAGEMENT AND ANALYSIS

- Data management

15:30 **COFFEE BREAK**

16:00 **Session 5 continued**

- Statistical analysis and reporting

Breakout session
- Topic: Use of computers and data analysis

Feedback from breakout session

18:00 END OF DAY TWO

FRIDAY | OCTOBER 8, 2010

08:30 **Session 6**

SYSTEMS AUDITS

- Pharmacovigilance
- Laboratory
- Phase I sites

Discussion

10:00 **COFFEE BREAK**

10:30 **Session 6 continued**

- Investigational Medicinal Product

Discussion

Breakout session
- Topic: 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

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:

Park Inn London Russell Square
92 Southampton Row
WC1B 4BH London
United Kingdom
Ph +44 207 400 3808
Fax +44 207 400 3817
http://www.london.russell-square.parkinn.co.uk/

at the special rate of:
Room in single use GBP 140.00
Room in double use GBP 150.00

These rates are per room and night and include service, taxes, VAT and buffet breakfast

To reserve a room, please use the hotel booking form on the DIA website or call the hotel.

IMPORTANT: To be assured of accommodation at the Park Inn Russell Square, registrants are recommended to complete their reservation by September 08, 2010 latest. Reservations received after that date are subject to availability.

DIA Upcoming Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD) at the European Medicines Agency
Courses throughout the year | European Medicines Agency, London, UK
For course details on EV, please visit www.diahome.org > Educational Offerings > EudraVigilance > Click on Related Courses

Non-Clinical Research

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

REGISTRATION FORM

Practical GCP Compliance Auditing of Trials and Systems
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ID# 10546

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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. **Registration will be accepted by mail, fax, email or online at www.diahome.org**

REGISTRATION FEES	MEMBER		NON-MEMBER (with optional membership)			NON-MEMBER (without optional membership)	
	FEE	TOTAL	FEE	MEMBERSHIP	TOTAL	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 of registration fees must be received before commencement of the training course.

Please indicate your areas of professional interest:

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- ❑ AH - Academic Health Centres
- ❑ AM - Alternative / Herbal Medicine
- ❑ BT - Biotechnology
- ❑ CD - Clinical Data Management
- ❑ CH - Chemistry / Drug Design
- ❑ CL - Clinical Laboratory Data
- ❑ CM - CMC
- ❑ CP - Clinical Safety/Pharmacovigilance
- ❑ CR - Clinical Research & Development
- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
- ❑ DE - Devices
- ❑ DM - Document Management
- ❑ FI - Finance
- ❑ EC - e-Clinical
- ❑ GC - GCP
- ❑ GE - Generic Manufacturing
- ❑ GL - GLP
- ❑ GM - GMP
- ❑ IM - Information Management
- ❑ IMP - Impact
- ❑ IS - Investigator Site
- ❑ IT - Information Technology / e-Business
- ❑ LA - Legal Affairs
- ❑ MA - Marketing / Advertising
- ❑ MC - Medical Communications / Information
- ❑ MH - Managed Healthcare
- ❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
- ❑ MW - Medical / Scientific Writing
- ❑ NC - Non-clinical Safety & Efficacy / Toxicology
- ❑ NH - Natural Health Products
- ❑ OS - Outsourcing / Virtual Development
- ❑ OT - Over the Counter
- ❑ PC - Pharmaceutics
- ❑ PD - Professional Development
- ❑ PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- ❑ PH - Pharmacology
- ❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- ❑ PM - Project Management
- ❑ PP - Public Policy / Law
- ❑ QC- Quality Control / Quality Assurance
- ❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- ❑ RD - Research & Development / Strategic Issues
- ❑ ST - Statistics / Biostatistics / Mathematical Modelling
- ❑ TR - Training
- ❑ VA - 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

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

PAYMENT METHODS

❑ **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: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
D.I.A., Elisabethenanlage 25, 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# 10546 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 worked with GCP for _____ years

I have no/or very limited experience with auditing experience ❑ 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

Registrants who do not cancel five working days prior to the course start date and do not attend, 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 registrants. Registrants 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 registrants 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	**Fax**	**Email**	**Mail**
www.diahome.org	+41 61 225 51 52	diaeurope@diaeurope.org	DIA European Office Postfach, 4002 Basel, Switzerland