OVERVIEW

This clinical trial audit course is designed to provide training on methods and approaches to plan, conduct and report on different types of audits with examples of practical implementation and discussion of challenges. Recent trends and updates in clinical trial legislation and guidance, increased use of electronic systems in clinical trials as well as implementation of risk management principles are imbedded.

The course is a combination of presentations, panel discussions and exercises by an experienced team of auditors and EMA and inspector representatives.

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 and report on trial specific and system audits
• Understand requirements for inspections
• Apply a risk based approach for the planning and conduct of audits

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

• Regulatory framework EU and ICH
• Quality management, defining quality
• Risk-based approach to audit and inspection planning and conduct
• 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 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 to clinical trial coordinators in a quality role at health institutions. The content may also benefit quality managers performing self-inspections.
DAY 1

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
- Risk-based 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
- Inspection reporting

14:45 COFFEE BREAK

15:15 SESSION 2 CONTINUED

- Discussion previous session
- Breakout session: Audit methodology and reporting
- Feedback from breakout session
- Discussion

17:15 DRINKS RECEPTION

18:15 END OF DAY ONE

DAY 2

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

- Data integrity from data collection to archiving
- Computer systems and standards
- Audit of computer systems
- Breakout: Investigator Site Audit
- Feedback from breakout session

14:50 COFFEE BREAK

15:20 SESSION 5

SELECTED SYSTEMS AUDITS

- Drug safety audit
- Investigational medicinal product (IMP) audit
- Discussion
- Breakout session: Systems audits methodology and reporting
- Feedback from breakout session

17:15 END OF DAY TWO

Continuing Education

DIA meetings and training courses 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.

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

Unless otherwise disclosed, DIA 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. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.
DAY 3

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  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

15:30  END OF TRAINING COURSE

Training Course venue
Holiday Inn London Kensington Forum
97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9094
http://www.hikensingtonforumhotel.co.uk/

DIA has blocked a limited number of hotel rooms for the course participants from 16 to 19 October 2016 at the rate of GBP 160.00 per single room per night including Full English Breakfast, taxes and service fee. In order to book a hotel room, please call the hotel directly and quote the booking reference “XNM”. The room rate is available until 12 September 2016 or until the room block is sold-out, whichever comes first. Cancellations received after 12 September 2016 will be subject to cancellation fee of 100% of the booking value.

About DIA
DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA’s scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients—join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

Follow @DrugInfoAssn

Find out more at DIAGlobal.org/Community
REGISTRATION FORM

Clinical Trial Audits in Practice #16531
17-19 October 2016 | Holiday Inn – Kensington Forum | London, UK

REGISTRATION FEES
Registration fee includes refreshment breaks and lunches and training course material. Please check:

<table>
<thead>
<tr>
<th>FEES</th>
<th>MEMBER</th>
<th>NON-MEMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDUSTRY</td>
<td>€ 1'870.00</td>
<td>€ 2'025.00</td>
</tr>
<tr>
<td>ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)</td>
<td>€ 935.00</td>
<td>€ 1'090.00</td>
</tr>
</tbody>
</table>

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

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

DIA MEMBERSHIP
All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diahome.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

☑ I do not want complimentary membership

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel.: +41 61 225 51 51 Fax: +41 61 225 51 52
Email: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

Cancellation Policy
All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks 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

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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.

There is a minimum number of participants required for this course. If the number of participants is lower than the required minimum, DIA reserves the right to cancel the course. If the course is cancelled, you will be informed as soon as possible and DIA will refund your course fee.

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 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 in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

ATTENDEE DETAILS

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

☑ Prof ☐ Dr ☐ Ms ☐ Mr

Last Name
First Name
Job Title
Company
Address
Postal Code
City
Country
Telephone Number
Fax Number

email (Required for confirmation) 
Attendee email (Required for course material access) 

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 # 16531 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, Middle East and Africa.

By signing below, I confirm that I agree with DIA’s Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date
Signature

© DIA 2016