

Good Clinical Practice

9-10 April 2018

Hilton Canary Wharf, London, United Kingdom



OVERVIEW

This practical clinical trial audit course is an opportunity to share experiences and develop skills in the methods and approaches to planning, conducting and reporting different types of audits.

With targeted discussions on regulatory hot topics, common challenges, audit trends and updates in clinical trial legislation and guidance, this course is a combination of presentations and discussions, and workshop exercises facilitated by an experienced team of auditors.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- Develop and apply a risk based approach for the planning and conducting audits
- Use common audit methodology principles when conducting audits
- Report on trial specific and system audits
- Report and provide value-added feedback to ensure robust corrective and preventative action plans
- Understand activities to be performed to ensure inspection readiness

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

- Risk-based approach to audit planning and conduct
- Quality management, Quality Control and Quality Assurance
- Trial audits in practice
- System audits in practice
- Regulatory framework EU and ICH
- Communication of audit findings
- Inspections by European and other authorities
- Evaluation of Corrective and Preventative Action Plans

WHO WILL ATTEND

This course is designed to provide practical audit conduct training for regulatory authority inspectors, auditors, monitors, professionals preparing for an audit or inspection and clinical trial coordinators in a quality role at health institutions.

The content may also benefit quality managers performing self-inspections.

Level: Intermediate, for professionals with 3-5 years' experience in auditing.

FACULTY

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Mirabilitas Ltd, UK

DAY 1

08:00 REGISTRATION

08:30 SESSION 1

INTRODUCTION

- Aims & Objectives

09:15 SESSION 2

REGULATORY FRAMEWORK

- EU and ICH

10:00 COFFEE BREAK

10:30 SESSION 3

INSPECTION 'HOT TOPICS'

- Common trends in inspection findings – types and classification

11:15 SESSION 4

QUALITY MANAGEMENT SYSTEM

- Quality Control & Quality Assurance

12:00 LUNCH BREAK

13:00 SESSION 5

QUALITY MANAGEMENT SYSTEM WORKSHOP

13:45 SESSION 6

RISK ASSESSMENT MANAGEMENT

- Risk based approach for conducting GCP audits

14:30 COFFEE BREAK

15:00 SESSION 7

GCP AUDITS

- Overview of various types of GCP audits

15:45 SESSION 8

AUDIT PLANNING

- Steps involved with audit planning including stakeholder management

16:30 NETWORKING RECEPTION

17:30 END OF DAY ONE

DAY 2

08:30 RECAP OF DAY 1

08:45 SESSION 9

AUDIT PLANNING WORKSHOP

10:00 COFFEE BREAK

10:30 SESSION 10

AUDIT CONDUCT

- Steps involved with audit conduct, including on-site and remote

11:15 SESSION 11

AUDIT CONDUCT WORKSHOP

12:00 LUNCH BREAK

13:00 SESSION 12

AUDIT REPORT

- Guide to writing good audit reports

13:45 SESSION 13

AUDIT REPORT WORKSHOP

14:30 COFFEE BREAK

15:00 SESSION 14

BUSINESS FEEDBACK & CORRECTIVE AND PREVENTATIVE ACTION PLANS

- Do's and Don'ts when writing CAPAs

15:45 SESSION 15

QUIZ

16:30 END OF TRAINING

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.

| Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

Training Course Venue

HILTON LONDON CANARY WHARF

South Quay, Marsh Wall
London, E14 9SH

Tel: +44 203 002 2300

Fax: +44 203 002 2350

Email: LONCW_Hotel@hilton.com

From London City Airport, take the Docklands Light Railway to Poplar station. Change at Poplar for a DLR train to South Quay station. The Hilton London Canary Wharf hotel is next to the station.

From the London Underground Canary Wharf Tube station, take the Jubilee Place main exit. Once out of the station turn left and proceed to the pedestrian traffic crossing. Cross the road and walk straight ahead towards the glass building, go through the glass building continuing to walk straight. Once out of the glass building walk up the little steps to cross over the footbridge, at the end of the footbridge turn left and walk straight and then turn right after first parking bays into Admirals Way. The hotel is situated towards the bottom of the road on your left hand side.



Accommodation

FRASER PLACE CANARY WHARF

80 Boardwalk Place

London, E14 5SF

Tel: +44 20 7068 7000

Fax: +44 20 7068 7020

Email: canarywharf@frasershospitality.com

For detailed rates please view the booking information file on DIA website.

To book an apartment please contact reservations department at Frasers Hospitality directly with a reference "DIA":

Tel: +44 20 7341 55 99

Fax: +44 20 7341 55 88

Email: sales.london@frasershospitality.com

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Basel@diaglobal.org for a custom group rate.

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11 credits.



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REGISTRATION FORM

Good Clinical Practice # 18531
9-10 April 2018 | Hilton Canary Wharf | London, United Kingdom



REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 <input type="checkbox"/>	€ 1'605.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 <input type="checkbox"/>	€ 880.00 <input type="checkbox"/>

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

Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.

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.diaglobal.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 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: Basel@diaglobal.org **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland

Web: www.DIAglobal.org

TERMS AND CONDITIONS

CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA 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.

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 AND VIDEO 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

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 #18531 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.**

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.diaglobal.org/EUTerms>

Date

Signature