DIA Learning

Trial Master File Inspection Readiness in Digital Era

Virtual Live Training Course

2-3 May 2023 13:00-17:30 CEST

OVERVIEW

For many organisations, clinical trial regulatory inspections are obligatory for achieving or maintaining market authorisation. However, it can be challenging for your organisation to sustain the required level of preparedness while simultaneously dealing with data integrity, data privacy and Good Clinical Practice (GCP).

This course teaches you oversight strategies for ensuring that you can sustain your inspection readiness throughout the clinical trial development process. Using practical examples, we will provide insights into helping your organisation prepare for an inspection in this digital era. We will also show you those areas of quality, data integrity and process improvement where you should focus your attention if you are to be ready to meet specific EMA, FDA and MHRA requirements.

LEARNING OBJECTIVES

On completing this course, participants will be able to:

- Identify the key areas of focus for inspections
- Realize how to ensure the organisation can remain inspection-ready at all times
- Assess the differences between the FDA, EMA, MHRA and other national authorities
- Determine the impact of GDPR has on managing Clinical Trials and establish Data Integrity
- Apply a risk-based approach to planning and conducting internal audits

WHO WILL ATTEND

This course is designed for professionals in academia and in the pharmaceutical, medical and biotechnology industries who are responsible for:

- Clinical operations representatives
- CROs, CMOs and service providers
- Document and records managers
- Internal/External Auditing
- Clinical Project Management
- Trial Master Files (TMF)
- Clinical Documentation Management
- IT and support personnel
- Quality assurance and compliance professionals
- Regulatory operations representatives
- Standards implementation specialists and associates
- Validation professionals
- Regulatory compliance specialists.

FACULTY

Marion Mays
Senior Vice President of Clinical
Kivo
USA

Louise Mawer
Director
Mirabilitas Ltd.
United Kingdom

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

13:00 WELCOME AND INTRODUCTION

13:15 SESSION 1

REGULATORY FRAMEWORK EU AND ICH REGION AND QUALITY MANAGEMENT

- Regulatory framework
- How do you define quality?
- Sponsor's Quality management system principles according to ICH E6(R2)
- Impact of further ICH GCP Changes (R3 compared to R2)

13:45 SESSION 2

INSPECTIONS BY EUROPEAN AND THIRD COUNTRY AUTHORITIES

- Inspections by European, US, and Third Country Authorities

14:30 SESSION 3

TRIAL AUDIT IN PRACTICE TO ENSURE INSPECTION READINESS

- Risk-based approach to audit and inspection
- Non-technical aspects of inspections
- What to expect for Remote Inspections

15:00 BREAK

15:15 SESSION 4

WHAT QUALITY MANAGEMENT PROCESSES SHOULD BE COVERED IN ORDER TO ENSURE THAT THE ETMF SYSTEM IS INSPECTION READY AND COMPLIANT?

- Biggest challenges to encounter when implementing eTMF
- Key implementation steps that impact eTMF inspection readiness?
- Gaps in documentation and how to avoid them?
- The impact of digitalization on your trial how to optimize processes and systems

16:15 SESSION 5

HOW TO ENSURE THAT ALL DOCUMENTS COMING FROM DIFFERENT SOURCES WITHIN THE SPONSOR SITE, VENDORS OR CROS ARE INSPECTION READY?

- Expectation of regulatory authorities
- Clarification on essential documents
- eTMF: visibility, transparency of documents, regulatory requirements, and expectancy from GCP inspectors.
- Internal eTMF reasons behind and how to implement it
- Access to data for Remote Inspections

17:15 QUESTIONS AND ANSWERS

17:30 END OF DAY ONE

DAY 2

13:00 SESSION 6

HOW TO ENSURE BEST CONSISTENCY IN TERMS OF FILING OF DOCUMENTS AND AVOID CRITICAL FINDINGS IN YOUR TMF BY INSPECTORS

- Practical Examples

13:30 SESSION 7

SPONSOR RESPONSIBILITIES FOR ETMF MANAGEMENT

- Technology requirements for Trial Master File management
- Investigator control over the TMF extends to archiving
- How to avoid unnecessary duplication
- Oversight requirements

14:00 SESSION 8

DATA INTEGRITY, DATA GOVERNANCE SYSTEM AND ITS COMPLIANCE WITH GDPR: HOW TO ESTABLISH IT?

- The eSource Data: regulatory requirements FDA/EMA
- Electronic Data Compliance with GDPR

14:45 BREAK

15:00 SESSION 9

CASE STUDY: EXAMPLES OF CRITICAL FINDINGS BY INSPECTORS AND LESSONS LEARNED

- Incompleteness of eTMF
- The CROs TMF and expectations
- Gaps in filing documents and how to avoid them

17:00 QUESTIONS AND ANSWERS

17:30 END OF THE TRAINING COURSE

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 has its Global Center 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

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary 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 does not apply to the already discounted fees for industry (early-bird), government or charitable nonprofit/academia.

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 via email to basel@diaglobal.org.

Follow **@DrugInfoAssn**

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 7.5 credits.

Technical Requirements

To test your system compatibility, please click on the link:
https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

REGISTRATION FORM

TMF Inspection Readiness Virtual Live Training Course # 23538
2-3 May 2023 13:00-17:30 CEST

DIA Learning

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **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 EARLY-BIRD valid until 6 March 2023	MEMBER valid from 7 March 2023	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 720.00 ❑	€ 800.00 ❑	€ 1'035.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 400.00 ❑	€ 635.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

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 nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

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.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

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

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 #23538 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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