DIA LEARNING

TMF Management, Oversight and Inspection Experience

Virtual Live Training Course

11-12 June 2025 | 13:00-17:30 CEST

Overview

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

This course shares with you TMF management and oversight strategies for ensuring that you can sustain your TMF inspection readiness throughout the clinical trial development process. Using practical examples, we will provide insights into helping your organisation prepare your TMF for an inspection in this digital era.

We will also show you those areas of TMF 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

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

- Identify the key areas of focus for inspection of the TMF
- Ensure the organisation can maintain TMF that are inspection-ready at all times
- Assess the differences and similarities between various authority inspections of the TMF
- Determine the impact GDPR has on managing Clinical Trial records and the TMF processes
- Apply a risk-based approach to planning and conducting audits of the TMF

Key Topics

- Regulatory Frameworks
- GCP TMF Inspections by Authorities
- Operational Considerations for TMF Inspection Readiness
- eTMF Inspection Readiness
- TMF Governance
- Filing Consistency and Avoiding Critical Findings
- Sponsor Responsibilities for Outsourced TMF Management
- Data Integrity, Data Governance and Compliance with GDPR

Who Will Attend

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

- Clinical operations representatives
- CROs, CMOs and service providers
- Document and records managers
- Clinical project managers
- Internal/external auditors
- Clinical documentation managers
- IT and support personnel
- Quality assurance and compliance professionals
- Regulatory operations representatives
- Standards implementation specialists and associates
- Validation professionals
- Regulatory compliance specialists

Faculty

Louise Mawer
Director, Mirabilitas, United Kingdom

Louise Mawer is a GxP quality assurance auditor and trainer, with over twenty years' experience in GCP, GLP and, more recently, GVP. A former UK Inspector for GCP and GLP, Louise spent seven years with the MHRA, before returning to the pharmaceutical industry in 2011 and establishing her own consultancy in 2013. Louise is Chair of the Quality Working Party of the European Forum for GCP (EFGCP) and a member of the Research Quality Association Research Practice Group. Louise has presented at national and international events, and developed training for GCP, GLP and GVP stakeholders and audit groups.

Marion Mays
CEO, Jerion Consulting, United States

Marion Mays in an industry leader in Information Management with over 25 years of experience in the Pharmaceutical industry. An advocate for essential information management practices; competent training for all contributors and consumers of the documentation which supports the advancement of clinical outcomes. Highly skilled in developing and implementing enterprise-wide programs and systems in regulated environments with proven record of success in technical problem solving. In-depth experience with quality and compliance processes in the pharmaceutical industry including supporting organizations through major regulatory inspections with FDA, MHRA, EMA, and PMDA.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

13:00 WELCOME AND INTRODUCTION

13:15 SESSION 1

TMF REGULATORY FRAMEWORKS

- Regulatory framework
- Sponsor's quality management system principles according to ICH E6(R2)
- Impact of ICH GCP changes (R3 compared to R2)

13:45 SESSION 2

GCP TMF INSPECTIONS BY AUTHORITIES

- Inspections by European, US, and third country authorities

14:30 SESSION 3

OPERATIONAL CONSIDERATIONS FOR TMF 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

IS YOUR ETMF INSPECTION READY?

- How digitalisation has changed TMF management
- Implementing your eTMF
- Practical examples of change management

16:15 SESSION 5

TMF GOVERNANCE

- Defining your TMF universe to meet regulatory expectations
- Control of the TMF and essential documents, including quality control, metrics and reports
- TMF oversight
- Common TMF isues and how they can be avoided

17:15 QUESTIONS AND ANSWERS

17:30 END OF DAY ONE

DAY 2

13:00 SESSION 6

FILING CONSISTENCY AND AVOIDING CRITICAL FINDINGS

- Practical examples
- Common TMF issues
- Grey areas

13:30 SESSION 7

SPONSOR RESPONSIBILITIES FOR OUTSOURCED TMF MANAGEMENT

- Technology requirements
- TMF oversight
- Archiving considerations

14:00 SESSION 8

DATA INTEGRITY, DATA GOVERNANCE AND COMPLIANCE WITH GDPR

- Electronic data: Regulatory requirements
- Compliance with GDPR

14:45 BREAK

15:00 SESSION 9

CASE STUDIES: AVOIDING CRITICAL FINDINGS

- TMF completeness

17:00 QUESTIONS AND ANSWERS

17:30 END OF THE TRAINING COURSE

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.

Group Discounts

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

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.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore eLearning to allow self-paced learning.

For more information please contact tereza.krucka@diaglobal.org

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

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

Continuing Education

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 7.50 credits.

REGISTRATION FORM

TMF | Virtual Live Training Course | # 25538
11-12 June 2025 | 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 16 Apr 2025	MEMBER valid from 17 Apr 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 900.00 ❑	€ 1'000.00 ❑	€ 1'260.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 500.00 ❑	€ 760.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats are limited.			

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 METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature