

PV Inspection Readiness for Global HQ

Virtual Live Training Course

18 November 2026 | 13:00-17:00 CET



Overview

Pharmacovigilance inspections by health authorities are a critical component of maintaining market authorisations and demonstrating the robustness of a company's pharmacovigilance system. For Global HQ functions, the stakes are particularly high – the ability to host, manage, and respond to inspections in different countries is a direct reflection of organisational maturity and regulatory standing.

This course equips Global HQ participants with the knowledge, strategies, and practical tools to achieve and sustain PV inspection readiness including the readiness to reply to questions related to AI implementation. It covers approach to the inspections to proactively identify compliance gaps before a regulatory visit occurs.

Participants will work through the full inspection lifecycle from the moment a notification is received, through the conduct of the inspection and management of authority interactions, to the submission of a credible CAPA response – all within a broader framework of continuous inspection readiness.

Learning Objectives

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

- Describe the inspection landscape – identify the legal basis and scope including possible sanctions for non-compliance.
- Apply a risk-based approach to inspection readiness – use audit and self-assessment techniques to identify gaps in the PV system and prioritise remediation activities before a regulatory visit.
- Prepare and manage inspection logistics at Global HQ – plan the inspection from notification through close-out, including documentation preparation, room management, and cross-functional coordination.
- Evaluate and manage PV documentation under inspection conditions – assess documentation quality and completeness, and handle situations involving missing, incomplete, or disputed records.
- Navigate complex inspection dynamics – manage communication with inspectors in challenging situations, handle disagreements on findings professionally, and maintain composure in high-pressure scenarios.
- Identify common inspection findings – recognise findings that are frequently cited understand how to prevent and address them.
- Develop and oversee a robust CAPA response – structure corrective and preventive actions that are credible, time-bound, and proportionate to the severity of findings, and establish follow-up mechanisms to verify effectiveness.
- Embed inspection readiness as an ongoing practice – apply strategies to sustain a state of continuous inspection readiness across Global HQ, including documentation governance, self-inspection programmes, and quality oversight routines.

Faculty

Marcela Fialova

COO
iVigee Services
Czech Republic

Lucia Matejkinova

QA Director
iVigee Services
Czech Republic

Who Will Attend

This course is designed for professionals in Global HQ roles who have governance, oversight, or operational responsibility within the pharmacovigilance system. It is particularly relevant for those in:

- Pharmacovigilance and Drug Safety (including QPPV office functions)
- Quality Assurance and Compliance
- Regulatory Affairs
- Risk Management
- Medical Affairs
- PV Operations and governance leads

A solid working knowledge of pharmacovigilance requirements is expected. Prior exposure to internal audits or health authority interactions is advantageous but not required.

DAY 1

13:00 WELCOME & COURSE INTRODUCTION

- Faculty introductions
- Course objectives

13:15 MODULE 1

THE PV INSPECTION LANDSCAPE

- Legal basis, scope, and authority frameworks
- Possible sanctions for non-compliance
- AI implementation readiness as an emerging inspection topic

13:50 MODULE 2

RISK-BASED INSPECTION READINESS

- Self-assessment and gap identification techniques
- Prioritising remediation before a regulatory visit
- Audit-based approaches to proactive compliance

14:30 BREAK

14:40 MODULE 3

LOGISTICS FOR PREPARING FOR AND MANAGING THE INSPECTION

- From notification to close-out
- Documentation preparation and room management
- Cross-functional coordination at Global HQ

15:15 MODULE 4

DOCUMENTATION AND INSPECTION DYNAMICS

- Evaluating PV documentation quality and completeness
- Handling missing, incomplete, or disputed records
- Managing inspector communication in high-pressure situations
- Handling disagreements on findings professionally

15:50 BREAK

16:00 MODULE 5

COMMON INSPECTION FINDINGS & CAPA RESPONSE

- Frequently cited findings
- Developing a credible, time-bound, and proportionate CAPA response
- Establishing follow-up mechanisms to verify effectiveness

16:30 MODULE 6

EMBEDDING CONTINUOUS INSPECTION READINESS

- Documentation governance
- Self-inspection programmes
- Quality oversight routines
- Sustaining readiness as an ongoing HQ practice

16:50 Q&A, WRAP-UP & CLOSE

17:00 END OF THE TRAINING COURSE



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.

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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

All DIA training courses have been awarded a PharmaTrain Centre Recognition.

PharmaTrain Federation is a not for profit organisation that started its activities as an IMI (Innovative Medicines Initiative) European Project. Its mission is to drive implementation of globally recognized high-level standards for postgraduate education and training in Medicines Development. To that aim, the Federation is assessing Continuous Professional Development (CPD) Courses and Course Providers around the world that deserve recognition.



REGISTRATION FORM

Global PV Inspection Readiness | Virtual Live Training Course | # 26593
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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 21 Oct 2026	MEMBER valid from 22 Oct 2026	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 360.00 <input type="checkbox"/>	€ 400.00 <input type="checkbox"/>	€ 660.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 200.00 <input type="checkbox"/>	€ 460.00 <input type="checkbox"/>

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.

DIA MEMBERSHIP

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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](https://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

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

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.

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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>.

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

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

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These are available from the office or online by clicking:

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Date	Signature
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