# DIA LEARNING

# Advanced Pharmacovigilance Audits and Inspections

## Virtual Live Training Course

### 3-7 November 2025 | 13:00-17:30 CET

## Overview

Using pharmacovigilance audit techniques allows a company to identify any existing gaps or risks in their systems and procedures. This allows them to define and establish priorities, ensuring brand protection and company compliance.

**Participants will learn how to prepare for an audit and inspection to achieve best practices from the moment of facing the auditing/inspection visit notification to the moment of receiving the report and its conclusions.**

## Learning Objectives

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

- Plan pharmacovigilance audits based on risk assessment
- Identify and address the different areas of a pharmacovigilance system through audits
- Conduct a pharmacovigilance audit
- Evaluate audit documentation
- Manage communication with difficult characters, situations with missing
- documentation and master extreme situations
- Handle disagreements on audit findings
- Identify and follow-up on corrective and preventive actions (CAPAs)
- Host and manage a pharmacovigilance inspection

## Who Will Attend

Those professionals most likely to benefit from this course will have experience in:

- Pharmacovigilance
- Drug Safety
- Regulatory Affairs
- Quality Assurance
- Risk Management
- Medical Affairs

or holding similar positions within the industry.

A sound knowledge of Pharmacovigilance is a must. Practical experience in audits and inspections is desirable.

## Faculty

**Calin Lungu**
CEO
Drug Development Consulting Services
Luxembourg

**Diane Hallé**
Senior Manager, Global Pharmacovigilance Quality Assurance
Alnylam
France

## Key Topics

- PV audits - QMS requirements from GVP
- PV audit planning
- Operating individual PV audits
- Affiliates and third parties
- Reconciliation process
- Computerised systems
- PV inspection readiness
- Management of PV inspection
- Management of post-PV inspection activities

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

# Schedule-At-A-Glance

## DAY 1

13:00   WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

13:30   SESSION 1

### PV AUDITS – QMS REQUIREMENTS FROM GVP

- EU QPPV
- PSMF
- KPI
- Contractual agreements
- Business continuity

**15:00   BREAK**

15:30   SESSION 1 CONTINUED

### PV AUDITS – QMS REQUIREMENTS FROM GVP

17:00   Q&A

17:30   END OF DAY 1

## DAY 2

13:00   SESSION 2

### PV AUDIT PLANNING

- Identify the different areas of the PV system to be audited
- Building a strategic and tactical PV audit planning
    - Case study: Identification of "PV audit universe"
    - Case study: Building strategic/tactical audit planning

**15:00   BREAK**

15:30   SESSION 3

### OPERATING INDIVIDUAL PV AUDITS

- General process (plan, prepare, conduct, report, follow-up and CAPA)

17:00   INTRODUCTION TO HOMEWORK FOR DAY 3

### CASE STUDY ON AUDITS OF AFFILIATES AND THIRD PARTIES

17:30   END OF DAY 2

## DAY 3

13:00   SESSION 4

### KEY PV AUDIT AREA 1: AFFILIATES AND THIRD PARTIES

- Audit planning (risk assessment, resources, audit team)
- Preparation (documentation requested in advance)
- Documentation audit e.g., PSURs
    - Case study review: Audit of affiliates and third parties

**15:00   BREAK**

15:30   SESSION 5

### KEY PV AUDIT AREA 2: RECONCILIATION PROCESS

- ICSR: Internal reconciliation and reconciliation with interfaces (medical information, complaints department)
- ICSR: Reconciliations with external entities (distributors, license partners, market research contractors, PSP services)
- Databases reconciliation: Pharmacovigilance or clinical databases

17:30   END OF DAY 3

## DAY 4

13:00   RECAP AND Q&A

13:30   SESSION 6

### KEY PV AUDIT AREA 3: COMPUTERISED SYSTEMS

- Principles and contents of validation dossier
- Validation team
- Risk analysis
- Design qualification
- IQ, OQ, PQ, PQ I & PQ II
- Validation report
- Maintaining the validated status of the database

**15:00   BREAK**

15:30   SESSION 7

### PV INSPECTION READINESS

- Checking resources (staff preparation, room and logistics)
- Running mock interviews with key staff
- Review of procedures
- Tour of facilities
- Remote audits and inspections

17:00   INTRODUCTION TO HOMEWORK FOR DAY 5

### EACH PARTICIPANT TO CHOOSE ONE CASE STUDY

- Case study on computerised systems or audits as preparation for a PV inspection
- Case study on inspection findings

17:30   END OF DAY 4

## DAY 5

13:00    REVIEW OF HOMEWORK CASE STUDIES

13:45    SESSION 8

### MANAGEMENT OF PV INSPECTION

- Logistics (staff preparation, room, recording document requests etc.)
- Do's and Don'ts during the inspection
- Disagreement with findings
- Closing meeting

14:15    BREAK

14:45    SESSION 9

### MANAGEMENT OF POST-PV INSPECTION ACTIVITIES

- Receiving inspection report
- Handling additional documents' requests post-inspection
- Answering to findings and CAPA
- Agreeing on timelines
- How to prepare for a re-inspection

17:30    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.

*\*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 basel@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 19.50 credits.

# REGISTRATION FORM

Advanced PV Audits and Inspections | Virtual Live Training Course | # 25551
3-7 November 2025 | 13:00-17:30 CET

**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 8 Sep 2025 | MEMBER valid from 9 Sep 2025 | NON-MEMBER |
|---|---|---|---|
| INDUSTRY/ REPRESENTATIVE | € 1'780.00 ❑ | € 1'980.00 ❑ | € 2'240.00 ❑ |
| ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME) | NA | € 990.00 ❑ | € 1'250.00 ❑ |
| 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**

## 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 |
|---|---|
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