DIA Learning

Advanced Pharmacovigilance Audits and Inspections

Virtual Live Training Course

21-25 October 2024 13:00-17:30 CEST

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

On completing this 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

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

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
Dr. Lungu has more than 30 years' experience in drug development, clinical research, Pharmacovigilance and quality assurance. He conducted almost 150 Pharmacovigilance quality system audits in more than 40 countries around the globe.

Diane Hallé
Senior Manager, Global Pharmacovigilance Quality Assurance
Alnylam
France
Dr. Hallé has more than 16 years of experience in PV for regulatory aspects, quality system and compliance, as well as for operational and project management activities. She held various positions at the French Agency, for more than 10 years as an inspector in PV, with more than 100 PV inspections to her credit. She is currently working for ALNYLAM dealing daily with PV audits and PV inspection readiness activities.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

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

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 19.5 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Technical Requirements

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

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

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.

Plan Your Team's Professional Development

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

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REGISTRATION FORM Virtual Live Training Course

Advanced Pharmacovigilance Audits and Inspections # 24551

21-25 October 2024 13:00-17:30 CEST

DIA Learning

REGISTRATION FEES

Registration fee includes full admission to virtual course 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 EARLY-BIRD valid until 26 August 2024	MEMBER valid from 27 August 2024	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 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.

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