DIA Learning

Advanced Pharmacovigilance Audits and Inspections
Virtual Live Training Course

26-30 September 2022 09:00-13:30 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 in order 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:

- Conduct a pharmacovigilance audit based on risk assessment
- Address the different areas through system audit
- Perform a process audit
- Interview and review audit documentation
- Deal with difficult characters, missing documentation and extreme situations
- Handle disagreements on audit findings
- Review and follow-up on corrective and preventive actions (CAPAs)

KEY TOPICS

- Global pharmacovigilance processes
- Reconciliation process, clinical and/or spontaneous
- Safety data exchange agreements (SDEA)
- Working with contractors (audit selection and audit in the process)
- Audits of affiliates and third parties
- System and process audits
- PSMF audits
- Computerised systems audits
- Audits as preparation for a pharmacovigilance inspection
- Preparing for and undergoing 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.

FACULTY

Patricia Bocciarelli
International Pharmacovigilance Expert
P. SUPP Consultant
France

Calin Lungu
CEO
Drug Development Consulting Services
Luxembourg

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

09:00 INTRODUCTION

09:30 SESSION 1

GLOBAL PV PROCESSES (PART I)
Patricia Bocciarelli
- Preparation for workshops 1 and 2
- PSMF (content, location, frequent findings)
- EU QPPV oversight on global and local processes, frequent findings

11:00   BREAK

11:30   SESSION 2

GLOBAL PV PROCESSES (PART II)
Patricia Bocciarelli

- Business continuity
- Interface of PV with Quality/Manufacturing
- Performance Indicators

13:30   END OF DAY 1

DAY 2

09:00 SESSION 3

SAFETY DATA EXCHANGE AGREEMENTS (SDEA) AND CONTRACTORS
Patricia Bocciarelli

- Concerned partnerships
- Methodology
- Surveillance
- Contractors: selection (audit or other method)
- Audit conduct (selection, in the process)
- Selection audit: clinical safety management contractor, Safety Management Plan

11:00   BREAK

11:30   SESSION 4

CASE STUDIES
Patricia Bocciarelli
- Workshop 1: How to build a strategic/tactical audit planning for EU QPPV oversight
- Workshop 2: Exercises on audit findings detection

13:30   END OF DAY 2

DAY 3

09:00 SESSION 5

AUDITS OF AFFILIATES AND THIRD PARTIES
Calin A. Lungu and Patricia Bocciarelli

- Audit Planning (risk assessment, resources, audit team)
- Preparation (documentation requested in advance)
- Documentation audit e.g. PSURs

10:30   BREAK

11:00   SESSION 5

CASE STUDY ON AUDITS OF AFFILIATES AND THIRD PARTIES
Calin A. Lungu and Patricia Bocciarelli

13:30   END OF DAY 3

DAY 4

09:00 SESSION 6

RECAP AND Q&A
Calin A. Lungu and Patricia Bocciarelli

09:30 SESSION 7

RECONCILIATION PROCESS
Calin A. Lungu

- ICSR: Internal reconciliation and econciliation 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

11:00   BREAK

11:30   SESSION 8

COMPUTERISED SYSTEMS AUDITS
Calin A. Lungu

- 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

13:00   INTRODUCTION TO HOMEWORK FOR DAY 5

CASE STUDY ON COMPUTERISED SYSTEMS AUDITS
Calin A. Lungu

13:30   END OF DAY 4

DAY 5

09:00 SESSION 9

REVIEW OF CASE STUDY ON COMPUTERISED SYSTEMS AUDITS
Calin A. Lungu

09:30 SESSION 10

AUDITS AS PREPARATION FOR A PV INSPECTION
Calin A. Lungu

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

10:15 BREAK

10:45 SESSION 11

EXPERIENCE DURING THE INSPECTION
Calin A. Lungu and Patricia Bocciarelli

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

12:00 SESSION 12

POST-INSPECTION FOLLOW-UP
Calin A. Lungu and Patricia Bocciarelli

- Receiving inspection report
- Handling additional documents' request post-inspection
- Answering to findings
- Agreeing timelines
- How to prepare for a re-inspection

13:30 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!

- 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, 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.

System Requirements

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

Operating Systems
- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements
- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers
- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed
- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

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.

Follow **@DrugInfoAssn**

REGISTRATION FORM Virtual Live Training Course

Advanced Pharmacovigilance Audits and Inspections # 22551
26-30 September 2022 09:00-13:30 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 1 August 2022	MEMBER valid from 2 August 2022	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'685.00 ❑	€ 1'870.00 ❑	€ 2'055.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 935.00 ❑	€ 1'120.00 ❑
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 CET. **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 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 #22551 as well as the invoice number to ensure correct allocation of your payment.

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