

# Advanced Pharmacovigilance Auditing and Inspections

## Virtual Live Training Course

2-6 November 2020 09:00-13:30 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 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  
Marta Gersberg Conseil  
France

#### Calin Lungu

CEO  
Drug Development Consulting Services  
Luxembourg

## DAY 1

### 09:00 INTRODUCTION

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### 09:30 SESSION 1

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#### 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

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### 11:30 SESSION 2

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#### GLOBAL PV PROCESSES (PART II)

*Patricia Bocciarelli*

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

### 13:30 END OF DAY 1

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## DAY 2

### 09:00 SESSION 3

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#### 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

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### 11:30 SESSION 4

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#### 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

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## DAY 3

### 09:00 SESSION 5

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#### 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

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### 11:00 SESSION 5

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

*Calin A. Lungu and Patricia Bocciarelli*

### 13:30 END OF DAY 3

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## DAY 4

### 09:00 SESSION 6

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#### RECAP AND Q&A

*Calin A. Lungu and Patricia Bocciarelli*

### 09:30 SESSION 7

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#### 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

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### 11:30 SESSION 8

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#### 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

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#### CASE STUDY ON COMPUTERISED SYSTEMS AUDITS

*Calin A. Lungu*

### 13:30 END OF DAY 4

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## 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

### 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

## 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, 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 Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 19.5 CPD credits.

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



### Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact [Basel@diaglobal.org](mailto:Basel@diaglobal.org).

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# REGISTRATION FORM

Advanced Pharmacovigilance Auditing and Inspections # 20551  
2-6 November 2020 09:00-13:30 CET



## 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	NON-MEMBER
INDUSTRY	€ 1'870.00 <input type="checkbox"/>	€ 2'025.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 935.00 <input type="checkbox"/>	€ 1'090.00 <input type="checkbox"/>
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](http://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](http://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](mailto:Basel@DIAglobal.org) **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland

**Web:** [www.DIAglobal.org](http://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>. You agree that your personal data will be transferred to DIA in the US.

## 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 #20551 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