

# Advanced Pharmacovigilance Auditing

9-11 April 2018

Hilton Canary Wharf, London, United Kingdom



## OVERVIEW

Through Pharmacovigilance Audit a company can identify the gaps or risks existing in the system and establish priorities in ensuring brand protection and company compliance.

You will learn how to prepare for an audit and an 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

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

- Make a PV audit based on risk assessment
- Cover the different areas through system audit
- Perform a process audit
- Interview and review audit documentation
- Deal with difficult characters, missing documentation, and extreme situations
- Manage disagreements on audit findings
- Review and follow-up on CAPAs

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

## KEY TOPICS

- Global PV processes
- Reconciliation process, clinical and/or spontaneous
- Safety data exchange agreements (SDEA)
- Contractors (audit selection and audit in the process)
- System and process audits
- PSMF audits
- Computerised systems audits
- Audits of affiliates and third parties
- Audits as preparation for a PV inspection
- Preparing and going through a PV inspection

## WHO WILL ATTEND

Professionals most likely to benefit from this training have experience in pharmacovigilance, drug safety, regulatory affairs, quality assurance, risk management, medical affairs or similar positions within the pharmaceutical industry.

## FACULTY

### Patricia Bocciarelli

International Pharmacovigilance Expert  
Marta Gersberg Conseil  
France

### Calin Lungu

CEO  
Drug Development Consulting Services  
Luxembourg

## DAY 1

08:00 REGISTRATION AND WELCOME COFFEE

08:30 SESSION 1

### GLOBAL PV PROCESSES (PART I)

Patricia Bocciarelli

- PSMF (content, location, frequent findings)
- Summary of PV systems
- EU QPPV oversight on global and local processes

10:00 COFFEE BREAK

10:30 SESSION 2

### GLOBAL PV PROCESSES (PART II)

Patricia Bocciarelli

- Business continuity
- Quality
- Performance Indicators
- Specific topics: periodic reports, signal detection

12:00 LUNCH

13:00 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)

14:00 COFFEE BREAK

14:30 SESSION 4

### CASE STUDIES

Patricia Bocciarelli

16:00 NETWORKING RECEPTION

17:00 END OF DAY ONE

## DAY 2

08:30 SESSION 5

### AUDITS OF AFFILIATES AND THIRD PARTIES (PART I)

Calin A. Lungu, and Patricia Bocciarelli

- Planning (risk assessment, resources, audit team)
- Preparation (documentation requested in advance)

10:00 COFFEE BREAK

10:30 SESSION 6

### AUDITS OF AFFILIATES AND THIRD PARTIES (PART II)

Calin A. Lungu, and Patricia Bocciarelli

- On site audit & common issues (language, collaboration from auditees, lack of time to cover all areas, findings & grading)
- Reporting and assessing the responses to audit findings
- CAPA follow-up

12:00 LUNCH

13:00 SESSION 7

### RECONCILIATION PROCESS

Calin A. Lungu

- ICSR: Internal reconciliation, Reconciliation with interfaces (Medical information, complaints department...)
- ICSR: reconciliations with external entities: distributors, license partners, market research contractors, PSP services...
- Databases reconciliation: PV/Clinical

14:30 COFFEE BREAK

15:00 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

16:30 END OF DAY TWO

### | 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).

## DAY 3

### 08:30 SESSION 9

#### 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

### 09:30 PRACTICAL EXERCISE (IN GROUPS)

### 10:00 COFFEE BREAK

### 10:30 SESSION 10

#### EXPERIENCE DURING THE INSPECTION

Calin A. Lungu

- Logistics (staff preparation, room, recording document requests etc.)
- Do and don't during the inspection
- Disagreement with findings
- Closing meeting

### 12:00 LUNCH

### 13:00 SESSION 11

#### POST-INSPECTION FOLLOW-UP

Calin A. Lungu

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

### 14:30 COFFEE BREAK

### 15:00 SESSION 12

#### CASE STUDIES

Calin A. Lungu

### 16:30 END OF THE TRAINING COURSE

## Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 17.5 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 17.5 credits.



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## Training Course Venue

### HILTON LONDON CANARY WHARF

South Quay, Marsh Wall  
London, E14 9SH  
United Kingdom

Tel: +44 203 002 2300

Fax: +44 203 002 2350

Email: [LONCW\\_Hotel@hilton.com](mailto:LONCW_Hotel@hilton.com)

**From London City Airport**, take the Docklands Light Railway to Poplar station. Change at Poplar for a DLR train to South Quay station. The Hilton London Canary Wharf hotel is next to the station.

**From the London Underground Canary Wharf Tube station**, take the Jubilee Place main exit. Once out of the station turn left and proceed to the pedestrian traffic crossing. Cross the road and walk straight ahead towards the glass building, go through the glass building continuing to walk straight. Once out of the glass building walk up the little steps to cross over the footbridge, at the end of the footbridge turn left and walk straight and then turn right after first parking bays into Admirals Way. The hotel is situated towards the bottom of the road on your left hand side.

## Accommodation

### FRASER PLACE CANARY WHARF

80 Boardwalk Place  
London, E14 5SF

Tel: +44 20 7068 7000

Fax: +44 20 7068 7020

Email: [canarywharf@frasershospitality.com](mailto:canarywharf@frasershospitality.com)

For detailed rates please view the booking information file on DIA website.

To book an apartment please contact reservations department at Frasers Hospitality directly with a reference "DIA":

Tel: +44 20 7341 55 99

Fax: +44 20 7341 55 88

Email: [sales.london@frasershospitality.com](mailto:sales.london@frasershospitality.com)

## Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted 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 only available for the industry rate.

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 to DIA.

For groups of 5 or more individuals, please contact [Basel@diaglobal.org](mailto:Basel@diaglobal.org) for a custom group rate.



# REGISTRATION FORM

Advanced Pharmacovigilance Auditing # 18551  
9-11 April 2018 | Hilton Canary Wharf | London, United Kingdom



## REGISTRATION FEES

Registration fee includes refreshment breaks, lunches 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"/>

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 non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit [www.diaglobal.org](http://www.diaglobal.org) and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

I do not want complimentary membership

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. **Tel.:** +41 61 225 51 51 **Fax:** +41 61 225 51 52

**Email:** [Basel@diaglobal.org](mailto:Basel@diaglobal.org) **Mail:** DIA, Kuchengasse 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.

### PHOTOGRAPHY AND VIDEO POLICY

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

## 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

Fax 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 #18551 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