DIA Learning

Advanced Pharmacovigilance Auditing

10-12 December 2018
Mercure Paris La Défense Grande Arche Hotel, Nanterre/Paris, France

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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

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.

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.

SwAPP Swiss Association of Pharmaceutical Professionals

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Training Course Venue

PARIS LA DÉFENSE GRANDE ARCHE

17/20 Esplanade Ch. de Gaulle
Rue des Trois Fontanot
92000 Nanterre (Paris region), France

Tel: +33 8 2580 5959
Fax: +33 1 4725 4624
Email: H1982@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 155.00 per standard room per night including breakfast and VAT, excl. City-Tax.
If you would like to make a booking, please fill in the booking form available on DIA website and send it per email to aziza.elkharraze@accor.com with a reference "DIA".
The room rate is available until 10 November 2018 or until the room block is sold-out, whichever comes first.
Note: The hotel is located right above the train station, and it is a bit noisy.

HOW TO GET THERE

From Charles de Gaulle airport take the Blue train line B towards city centre and get off at Chatelet.
Change there to Red train line A towards Cergy/Poissy/St. Germain en-Laye and get off at Nanterre Prefect.
The hotel is located right next to the train station.
Paris train/metro map (the Nanterre Prefect station/hotel is located just outside this map, left from the square A2)

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 for a custom group rate.

REGISTRATION FORM

Advanced Pharmacovigilance Auditing # 18553
10-12 December 2018 | Mercure Paris La Défense Grande Arche Hotel | Paris, France

DIA Learning

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 ❑	€ 2'025.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 935.00 ❑	€ 1'090.00 ❑

All registration fees are subject to applicable French VAT

Please enter your company's French 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 non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click here. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no aditional cost**

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 **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 here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. 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 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 #18553 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