DIA Learning

Advanced Pharmacovigilance Auditing

20-22 November 2019
Hotel Berlin Mitte, Berlin, Germany

OVERVIEW

Performing a Pharmacovigilance Audit assists companies to identify gaps or risks in the existing system and to establish priorities in ensuring brand protection and company compliance.

In this advanced training course, you will learn to identify the main pharmacovigilance issues and 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:

- Conduct a PV audit based on risk assessment
- Perform a process audit
- Manage auditees interviews, review audit documentation and prepare audit report
- Handle behavioural challenges and extreme situations
- Manage disagreements on audit findings
- Review and follow-up on Corrective and Preventive Actions (CAPAs)

Participants will complete a knowledge check at the end of the course to ensure learning objectives are attained.

KEY TOPICS

- Main global Pharmacovigilance processes
- Performance indicators implementation
- Reconciliation process, clinical and/or spontaneous
- Safety data exchange agreements (SDEA)
- Contractors management (audit selection and audit in the process)
- Audit planning risk assessment
- System audits
- Phamracovigilance System Master File (PSMF) audits
- Computerised systems audits
- Audits of affiliates and third parties
- Audits as preparation for a Pharmacovigilance inspection
- Preparing and going through a Pharmacovigilance inspection

WHO WILL ATTEND

Professionals most likely to benefit from this training have experience in pharmacovigilance but not necessarily a strong experience in audits and willing to learn/improve audit technical aspects. Drug safety personnel target to be ready facing pharmcovigilance audits and ispections. If you hold a position in regulatory affairs, quality assurance, risk management, medical affairs or similar positions within the pharmaceutical industry you would definitely profit from attending this couse.

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

08:30 SESSION 1

GLOBAL PV PROCESSES (PART I)

Patricia Bocciarelli

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

10:00 COFFEE BREAK

10:30 SESSION 2

GLOBAL PV PROCESSES (PART II)

Patricia Bocciarelli

- Business continuity
- Interface with Quality
- Performance Indicators

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)
- Selection audit: clinical safety management contractor. Safety Management Plan.

14:00 COFFEE BREAK

14:30 SESSION 4

CASE STUDIES

Patricia Bocciarelli

- Workshop 1: How to build a strategic/tactical audit planning
- Workshop 2: Exercises on audit findings detection

16:30 END OF DAY ONE

DAY 2

08:30 SESSION 5

AUDITS OF AFFILIATES AND THIRD PARTIES (PART I)

Calin A. Lungu, and Patricia Bocciarelli

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

10:00 COFFEE BREAK

10:30 SESSION 5

AUDITS OF AFFILIATES AND THIRD PARTIES (PART II)

Calin A. Lungu, and Patricia Bocciarelli

- Which documentation to request to auditees: Audit of affiliates
- Behavioural challenges
- Reporting and assessing the responses to audit findings
- CAPA follow-up

12:00 LUNCH

13:00 SESSION 6

CASE STUDIES

Calin A. Lungu

- Workshop 3: System audits including processes (signal detection, periodic reports etc) findings and CAPA

14:00 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

15:00 COFFEE BREAK

15:30 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

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

Training Course Venue

HOTEL BERLIN MITTE
(MANAGED BY MELIA)
Chausseestrasse 33
10115 Berlin, Germany
Tel: +49 30 41 47 230
Email: hotel.berlin.mitte@melia.com

Participants are kindly requested to contact hotel directly for the best available rate.

HOW TO GET THERE
The closest U-Bahn station is "Naturkundemuseum" on line U6 Alt-Tegel - Alt-Mariendorf.
From Tegel Airport take the bus TXL 128 towards Osloer Strasse, and get off at Kurt-Schumacher-Platz U-Bahn station.
Change there to U-Bahn line 6 towards Alt-Mariendorf and get off at Naturkundemuseum (8 stops).

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.

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