PVpharm

Pharmacovigilance services for the Pharmaceutical Industry

PHARMACOVIGILANCE TRAINING

V Edition

Join us to learn about the latest Pharmacovigilance updates

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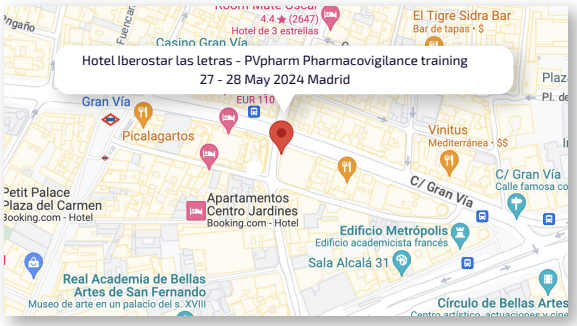
KEY TOPICS

- QPPV day-to-day activities
- PV in global and local context
- PRAC (Pharmacovigilance Risk Assessment Committee)
- Safety Referrals
- RMPs
- Pharmacovigilance
- Business models and integration of PV systems
- Patient safety
- Pharmacovigilance with innovative, generics and biosimilar products
- aRMM meausures, Dear Health Care Professional communications
- News on EMA, EudraVigilance, XEVMPD, EVDAS, Signal Management, CTIS
- Experiences from inspections and audits of the MAH, PV local functions, service providers and partners
- Artificial Intelligence in Pharmacovigilance
- Your own input (please send questions in advance to the speakers!)
- Much more…

WHEN & WHERE

The training will take place next **May 27th and 28th in Madrid**, Spain. Join us at the **Hotel Iberostar las Letras**, located in the city center of Madrid, great location to host this training, to connect with the rest of attendees and to enjoy the city.

Web hotel Iberostar



COURSE OBJECTIVES

This year, the 5th edition of the PV Training come with outstanding speakers with many years of experience in pharmacovigilance. They will help participants to improve their performance and knowledge in PV. The new training will focus on different areas both from the industry and the regulators' perspective.

The attendees will have the opportunity to send their questions in advance to the speakers, therefore, they will leave the course with all the information and questions solved!

As in previous editions, this training provides a fantastic environment to both improve your skills in PV and to socialize with other PV colleagues. Don't miss this networking opportunity.

Please, see the agenda to review the objectives of the presentations!

REASONS TO ATTEND

- Improve your knowledge on Pharmacovigilance EU Regulations.
- Get real examples on how other experienced PV professionals organize and manage the activities in the PV department.
- In deep review of the QPPV function in a MAH. From theory to real life examples.
- Learn how other MAHs organize pharmacovigilance activities.
- Stay tuned with the last news from EMA. Understand the implications for MAHs.
- Get updated on EMA, Eudravigilance, EVWeb, XEVMPD, EVDAS, CTIS and PRAC.
- Get deep understanding about benefit risk evaluation.
- Understand aRMMs, DHCP communications and how to do them.
- Learn about PV inspections and audits.
- Understand what Artificial Intelligence would mean in Pharmacovigilance.
- Send your questions in advance to the speakers.
- Solve your doubts in the proper forum.
- Improve your PV operations and compliance.
- Get to know what you are doing properly and what you need to improve.
- Feel more confident in your pharmacovigilance day-to-day.
- Enlarge your PV network.

WHO SHOULD ATTEND

- Professionals from MAHs
- Senior Managers and Pharmacovigilance managers
- QPPVs and LSOs
- Pharmacovigilance Officers/Drug Safety Specialists
- Directors/CEOs of CROs
- Regulatory/Inspection/Audits departments
- Anyone working in areas affected by Pharmacovigilance operations
- Pharmaceutical industry specialists
- People aimed to get a background in Pharmacovigilance

WHAT THE TRAINING INCLUDES

- 2 days or 1 day training
- Presentations in digital format
- Lunches, refreshment breaks and face-to-face networking for free for face-to-face participants
- Online and interactive training sessions for the remote participants

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FACULTY

JULIA APPELSKOG

EU QPPV, Hear of EU QPPV Office, NOVAVAX

Global PV leader with over 19 years experience leading all facets of PV operations in healthcare sector. Demonstrated expertise in risk management plans (RMPs), periodic safety update reports (PSURs), post-marketing PV commitments, signal detection, PASS, PV inspections, GVP and GCP audits, Quality Management System, ARGUS/A-RISg/Veeva safety databases, XEVMPD database and safety study protocols.

Strategic thinker with proven capacity to implement effective EU QPPV and PV strategies in adherence with industry best practices, trends, and legislation requirements to meet shared and individual goals. Adept at biological, biopharmaceuticals products, including vaccines, OTC, generics, cosmetics, and medical devices. Articulate and refined communicator establishing robust relationships with all levels of management.

RICARDO ANDRADE

Co-founder, Managing Director, OWL Pharma

Ricardo Andrade (PharmD; PGDip in Pharmaceutical Marketing Management and PGDip in Regulation and Evaluation of Medicines and Health Products) started working at INFARMED (Portuguese Health Authority) and then moved to the Pharmaceutical Industry. Since 2013 he is Co-Founder and Managing director at Owlpharma Consulting. He has been working in the Pharmaceutical Industry for over 15 years, particularly in Pharmacovigilance and Regulatory Affairs. He acts as EU QPPV and Local Contact in Portugal for several national and international pharmaceutical companies. He has an excellent knowledge of Pharmacovigilance legislation and is a regular trainer at the request of several pharmaceutical companies. His extensive experience in Pharmacovigilance includes Pharmacovigilance audits, signal management, implementation, and management of Pharmacovigilance systems.

PILAR CARRERO

Vice President Global Safety, LEO PHARMA

Experienced and accomplished senior leader with a broad skill set spanning research, pharmacovigilance, quality assurance, training, IT/digitalization, and recently, medical information, across diverse global settings. Known for adaptability and building strong stakeholder relationships. Recognized as a creative thinker who focuses on the big picture while maintaining a results-driven approach. Successfully drove the implementation of a new safety database and established two new departments from scratch, showcasing adept change management, offshore operations, and stakeholder engagement.

MARÍA JOSE RENESES SETIEN

Deputy EU QPPV, TAKEDA

Engaged with Pharmacovigilance for more than 20 years, she is Deputy EU QPPV at Takeda. Supervises the management of the PSMF, oversight of the PV quality management system, ensuring PV inspection readiness. Together with the EUQPPV, maintains oversight of the EU PV system, serve as the Deputy Qualified Person for Pharmacovigilance for the European Union.

SOFIA CAVERO

Senior Quality Specialist for Global Pharmacovigilance & Drug Safety, INSUD PHARMA

Pharmacist, with expertise in the quality system of the pharmacovigilance area. I add to the pharmacovigilance systems, and during GVPs inpections, my previous experience and knowledge in the quality assurance area of GMPs, GDPs, ISO Norms or medical devices at pharmaceutical multinational companies, where I've managed audits, service providers, procedures, corrective and preventive actions and the rest of the topics of a quality system. Project management in different countries.

FACULTY

JAN PETRACEK

CEO, iVigee

Jan is a passionate and visionary leader in the field of pharmacovigilance, with over 20 years of experience in the industry. He is the CEO of iVigee, a company that provides innovative and sustainable solutions for drug safety and risk management. He is also a Fellow of the International Society of Pharmacovigilance (FISoP), a Global Fellow in Medicines Development (GFMD), and a Qualified Person for Pharmacovigilance (QPPV).

Jan has a proven track record of establishing, growing, and selling successful organizations, both for-profit and non-profit, in the pharmacovigilance sector. He has received multiple awards and recognitions, including the DIA Excellence in Service Award in 2018 and the Queen's Award for International Trade in 2019. He is also a lecturer, trainer, auditor, and advisor for various pharmacovigilance courses and initiatives, and a founder of the Institute of Pharmacovigilance. Jan's mission is to elevate the recognition and competence of the pharmacovigilance profession, and to deliver sensible and pragmatic solutions to his clients and partners.

JOSÉ ALBERTO AYALA ORTIZ

PVpharm CEO, Pharmacovigilance Consultant, QPPV, PV Auditor

José Alberto Ayala Ortiz (M.Sc. Pharm. and M.Sc. IT) has been working for 20 years in Pharmacovigilance and Drug Safety. He has experience both from the Regulatory (Danish Medicines Agency), and from the Pharmaceutical Industry, where he has been responsible for Pharmacovigilance IT systems, databases and electronic transmissions. Besides his day-to-day Pharmacovigilance work as a consultant and PV auditor, he is trainer of EVWeb, XEVMPD and the DIA Signal Management training courses. He provides EU QPPV services and local QPPV in Spain for Pharmaceutical Companies and other consultancies through PVpharm, where he is the CEO.

MARTA RODRÍGUEZ VÉLEZ

Quality Assurance in the Sterile Manufacturing Site (vaccines), LETI Pharma

Marta is a Biologist, Master's Degree in Pharmaceutical Industry and Master's Degree in Business Administration. Passionate about science, health and technology, and throughout her professional career she have specialized in the pharmaceutical and life sciences industry. During her 20 years of professional life, she has always been linked to the pharmaceutical industry, managing projects related with basic research, clinical trials, quality assurance, compliance with GXP standards, regulatory affairs and pharmacovigilance.

CALIN LUNGU

Drug Development Consulting Services S.A. (DDCS), Luxembourg

Dr. Lungu has worked for more than 20 years in drug development, clinical research, pharmacovigilance and quality assurance. He has done over 150 PV audits. Since 2004 he is a EudraVigilance trainer and trained more than 250 Eudravigilance and XEVMPD courses at the EMA, selected European cities and also in the US. He has also trained from 2008 to 2012 the EudraVigilance Data Analysis System course at the EMA and including participants from the EMA and the National Competent Authorities.

ELSPETH MCINTOSH

Director /Consultant, CASTLE PHARMACOVIGILANCE

Elspeth McIntosh began her career in the pharmaceutical industry in 1993, initially working in clinical research, before moving into Pharmacovigilance. She has extensive experience of all aspects of pharmacovigilance and has been a small company QPPV since 1999, dealing with innovative, generic and biotech/biological products. Elspeth set up Castle Pharmacovigilance in 2009 and post Brexit she is a UK QPPV and UK National Contact Person for several small pharma companies and provides general PV support to a wide range of pharma companies.

DAY 1
27 MAY 2024

9:00-9:15 **WELCOME AND REGISTRATION**

9:15-9:45 **Introduction and overview of the agenda – Keynote: GVP, impact of new technologies and AI in PV**
Jose A. Ayala Ortiz
In this keynote you will learn about the latest updates and news on the application and the impact of Artificial Intelligence in the field of Pharmacovigilance. There will be a focus on GVP guidelines, how pharma companies are using the latest technology, potential applications and ethical considerations of the use of Artificial Intelligence in Pharmacovigilance.

9:45-10:30 **PV systems best practices – beyond the guidelines**
Ricardo Andrade
In this presentation you will learn about best practices in Pharmacovigilance. We will go beyond the GVP guidelines and will focus on practical experiences.

10:30-11:00 **COFFEE BREAK**

11:00-11:45 **Artificial Intelligence in Pharmacovigilance, QPPV perspective**
Julia Appelskog
In this presentation Julia will share her perspective as a QPPV on the use of Artificial Intelligence tools in Pharmacovigilance.

11:45-12:30 **Artificial Intelligence in Pharmacovigilance, practical considerations and examples**
Jan Petracek
Jan will share with us practical examples on the use of Artificial Intelligence in Pharmacovigilance.

12:30-13:00 **ROUNDTABLE**
Ricardo Andrade, Julia Appelskog, Jan Petracek and Jose A. Ayala Ortiz (moderator)
The roundtable will allow participants to make questions on the topics covered in the sessions.

13:00-14:00 **LUNCH BREAK**

14:00-14:45 **EudraVigilance, EMA, XEVMPD, EVDAS, Signal Management, PRAC, CTIS Updates**
Calin Lungu
In this session you will learn about the latest news, updates and requirements from EMA systems, including systems and topics related to: EudraVigilance, EVWeb, XEVMPD Art 57, EVDAS Signal Management, CTIS, OMS, SPOR, IDMP, PRAC, Service desk and many others.

14:45-15:30 **Pharmacovigilance in the UK post BREXIT**
Elspeth McIntosh
Elspeth will update us on the PV landscape post-BREXIT, including the most recent information from MHRA

15:30-16:00 **COFFEE BREAK**

16:00-16:45 **PSMF & Global PSMF**
María José Reneses
In this presentation María José will provide guidance on the Pharmacovigilance System Master File, and will share practical considerations about it.

16:45-17:15 **ROUNDTABLE**
Calin Lungu, Elspeth McIntosh, María José Reneses and Jose A. Ayala Ortiz (moderator)
The roundtable will allow participants to make questions on the topics covered in the sessions.

DAY 2
28 MAY 2024

9:00-9:45 **Implementation of a new Safety database at Leo Pharma**
Pilar Carrero
In this session, Pilar will share with us the experiences derived from the challenging project of the implementation of a new Safety database at Leo Pharma.

9:45-10:30 **The QPPV role**
Elspeth McIntosh
In this session Elspeth will guide us with an exhaustive overview of the QPPV role, including legal considerations, practicalities, oversight and a perspective on Local QPPVs.

10:30-10:45 **COFFEE BREAK**

10:45-12:15 **Risk Management in Pharmacovigilance**
Jan Petracek
In this presentation, Jan will share with us detailed guidance and practicalities on Risk Management in Pharmacovigilance.

12:15-12:45 **ROUNDTABLE**
Pilar Carrero, Elspeth McIntosh, Jan Petracek and Jose A. Ayala Ortiz (moderator)
The roundtable will allow participants to make questions on the topics covered in the sessions.

12:45-14:00 **LUNCH BREAK**

14:00-14:45 **Pharmacovigilance Quality Management Systems**
Marta Rodríguez
In this presentation, Marta will share consideration and practical examples on the topic of Quality Management in Pharmacovigilance.

14:45-15:30 **GVP Inspections, considerations from the pharmaceutical industry**
Sofia Cavero
In this presentation, Sofia will share with us practical experiences from recent competent authority inspections.

15:30-15:45 **COFFEE BREAK**

15:45-16:30 **Pharmacovilance Audits**
Calin Lungu
This presentation will provide learnings related to Pharmacovigilance Audits. Calin, as an expert auditor will share guidance considerations and practical experiences.

16:30-17:00 **ROUNDTABLE**
Marta Rodríguez, Sofia Cavero, Calin Lungu and Emma Cebrian (moderator)
The roundtable will allow participants to make questions on the topics covered in the sessions.

17:00-17:15 **FINAL NOTE AND CLOSURE**

REGISTRATION FEES

The registration fee includes training and course material in digital format. Participants that choose the face-to-face option will also receive refreshment breaks and lunches. Online and interactive training sessions for the remote participants.

Standard 2 days: **990€**

Standard 1 day: **550€**

Offers:
Early Bird (Until 26th April): 15% discount on Standard fee
Reduced fee for SME: 20% discount on Standard fee
Register 2 individuals from the same company and receive a 20% discount from the standard fee.
Offers are non-cumulative, only the most beneficial one would apply
Please also consult our special fees for University students/unemployed (upon presentation of documentation): info at trainingservices@pvpharm.com

REGISTRATION FORM

Please complete and send the form to **trainingservices@pvpharm.com**

Modality: ○ Face-to-face in Madrid ○ Online **Number of days:** ○ Two days (full) ○ One day

Your Name (required)

Company

Job Title

Phone

Email (required)

Your message (required)

Payment will be made by: ○ Company ○ Individual

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CANCELLATION POLICY

All cancellations must be made in writing two weeks prior to the event start date. If you do not cancel two weeks prior to the event start date and do not attend, you will be responsible for the full registration fee. You may transfer your registration to a colleague of the same organization before the course start.
If the minimum of participants is not reached two weeks prior to the event start, PVpharm reserves the right to cancel the event or alter the venue and dates if necessary. If an event is canceled or postponed, the cost will be incurred by registered attendees. Registered attendees are responsible for canceling their own hotel and travel reservations.

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