PVpharm

Pharmacovigilance services for the Pharmaceutical Industry

PHARMACOVIGILANCE TRAINING

IV Edition

Join us to learn about the latest Pharmacovigilance updates

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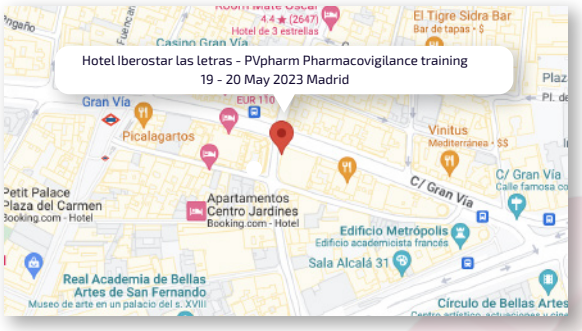
KEY TOPICS

- QPPV day-to-day activities
- PV in global and local context
- PRAC (Pharmacovigilance Risk Assessment Committee)
- Safety Referrals
- RMPs
- Clinical safety
- Pharmacovigilance
- Business models and integration of PV systems
- Patient safety
- Pharmacovigilance with innovative, generics and biosimilar products
- Safety in drug-device combination products
- 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 **June 19th and 20th 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 4th 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 (post-marketing and clinical safety commitments). From theory to real life examples.
- Understanding the PRAC: overview and in deep review of those activities with major impact on the MAHs: Safety Referrals procedures and Risk Management activities.
- 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.
- Understand DHCP communications and how to do them.
- Drug-device combination safety topics
- Learn about PV inspections.
- 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

ALEXANDRA SPURNI

Senior Manager - PV Regulatory Compliance, Accord Healthcare

Senior Manager for Regulatory Compliance, EMENA region at Accord Healthcare, joined EMA's Safety Committee – PRAC, as member for Romania between January 2019 and February 2023. Senior Pharm. (Clinical Pharmacy sp.), with an ongoing PhD on Toxicology area, with more than 10 years of experience in drug safety.

IVÁN ARIAS GARCÍA

PV Associate Director for Chemo & Xiromed, EU & UK QPPV

Linked to the pharmaceutical industry since 2007 and always in the Pharmacovigilance area, going through different positions and companies, both national and multinational and with a wide variety of products (innovative medicines, biosimilars, generics, medical devices, cosmetics and food suplements) to become EU & UK QPPV of CHEMO (part of the INSUD PHARMA). Currently manages a large team of people located in different countries, with great cultural differences, working conditions and time zones.

GEMMA JIMÉNEZ SESÉ

Director of Corporate Patient Safety, EUQPPV, Almirall

Gemma Jimenez Sese is the EU-QPPV for Almirall since 2011 and is based in Barcelona, Spain. Pharmacist by education, after a short period in hospital research moved to pharma industry working in UK and Spain, first in regulatory affairs and for the last 20 years in pharmacovigilance taking up roles with increasing responsibility. In PV she has been involved in a broad scope of activities, from safety in development to marketed medicinal products support, from small mollecules to biologics. Passionate about science and strong believer in our mission of putting always the patient first.

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.

JOAN D'SOUZA

Pharmacovigilance Consultant

Dr. Joan D'souza has pre and post-marketing safety surveillance experience. A firm believer in sharing her knowledge: The International Society of Pharmacovigilance (ISoP), Global Pharmacovigilance Society, American Medical Writers Association, European Medical Writers Association, and Pharma International Conferences in Europe are just a few of the many venues in which she has spoken. She has worked for various clinical research organizations and pharmaceutical companies. Her treatment experience includes oncology, dermatology, pain management, infectious disorders, vaccines, and diabetes.

Joan currently chairs the ISoP Switzerland and Austria Chapter. She is active in several ISoP special interest groups, including Risk communication (secretary), Medical devices, Geriatric pharmacovigilance, Vaccination, Medication error, and Ecopharmacovigilance. She also actively participates in the Pharmacovigilance and Medical devices special interest groups of the European Medical Writers Association. She frequently writes for the European Medical Writers Association Journal and the ISoP Drug Safety Journal. Currently, she is currently pursuing her passion in drug-device combination (DDC) products.

FACULTY

PANOS TSINTIS

Medical Director at PLM Med Ltd & PLM Med EU Ltd

Dr Panos Tsintis qualified and trained in internal medicine in the UK. He has over 30 years' experience in Pharmacovigilance and drug development. Panos is a former senior regulator with the European Medicines Agency (EMA) and UK MHRA. He currently runs his own consulting company PLM Med Ltd. Panos acts as senior advisor to CIOMS and is a member of working groups on Risk Minimisation, Patient Involvement and Benefit-Risk of medicines.

SARAH DANIELS

VP, Head of Safety Science, TranScrip

Sarah is one of tranScrip's key specialists in Pharmacovigilance and clinical safety and was formerly the EU QPPV for Roche. She has almost 30 years of industry experience and is a drug development and medical affairs expert in several therapeutic areas including oncology, virology and CNS.
Sarah is a UK registered pharmaceutical physician with diverse pharmaceutical industry experience gained in blue chip companies at both local and global level. She is a seasoned clinical safety physician and has been the clinical safety lead for several successful indication expansion programs in the oncology arena, including breast cancer and Non-Hodgkin's Lymphoma. She has also provided safety support in various clinical developmental programs including prostate cancer, malignant melanoma, community acquired pneumonia, and more recently Covid-19 trials.
Whilst she was the EU QPPV at Roche she successfully led the company through a series of EU Pharmacovigilance Inspections. Before this, she held the joint responsibilities of Head of the UK Drug Safety Centre and Deputy QPPV.

SUZANNE NIJENHUIS

Consultant Pharmacovigilance, DADA Consultancy B.V.

Suzanne Nijenhuis has a master's degree in Medical Biology. In 2020, Suzanne joined DADA as Consultant PV and brought more than 15 years of Pharmacovigilance experience to the company. Since 2023, she is a member of the Quality Compliance Training team and supports in quality control for all pharmacovigilance processes in DADA. Furthermore, she is involved in medical device vigilance, acts as EU-QPPV and coordinates the local PV vendors that are linked to DADA's pharmacovigilance system.

ILARIA GRISONI

Executive Director, Head of EU/International PV & Global Risk, Management and EEA QPPV at Jazz Pharmaceuticals

Ilaria is currently Executive Director, Head of EU/International PV and QPPV Office at Jazz Pharmaceuticals. She also covers the role of EEA QPPV for Jazz. Ilaria is a member of the Global Regulatory Affairs & Drug Safety (GRADS) Leadership Team at Jazz and leads the EU/International QPPV Office, ensuring PV oversight of affiliates and business partners in EU and International territories.
She has 15 years of experience in the pharmaceutical industry, with extensive experience in Pharmacovigilance, including participation into several inspections by European and non-EU regulatory authorities.
Ilaria is an active member of national and international PV working groups, including Farmindustria, Simef, DIA, PV Connect (Navitas Life Sciences). She is a member of the Scientific Board of the Italian PV Day, and participates as a speaker at conferences and seminars in the field of Pharmacovigilance.
She is one of the authors of the PIPA guidelines on PSMF Preparation and Management (2022).

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.

DAY 1
19 JUNE 2023

8:30-9:00 **WELCOME AND REGISTRATION**

9:00-9:30 **Introduction and overview of the agenda – Keynote: Artificial Intelligence in Pharmacovigilance**
Jose A. Ayala Ortiz
In this keynote you will learn about the latest updates and news on the application of Artificial Intelligence in the field of Pharmacovigilance. There will be a focus on how pharma companies are using the latest technology, potential applications and ethical considerations of the use of Artificial Intelligence in Pharmacovigilance.

9:30-11:00 **PRAC Updates. Overview of activities in The Pharmacovigilance Risk Assessment Committee PRAC and Safety Referrals**
Alexandra Spurni
In this presentation an overview of the activities covered by the PRAC mandate will be provided, including the legal framework and guidelines, the composition of the committee, its basic principles and toolbox. All the major procedures dealt with by the PRAC will be described in brief, including referrals, assessments, signal detection, RMPs, exemplified with real life case examples and latest decisions and updates.

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

11:30-12:15 **Update of the EMA systems**
Calin Lungu
In this presentation 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, Service desk and many others.

12:15-13:00 **Management of the Pharmacovigilance Department – Big generic company perspective**
Ivan Arias
In this presentation you will learn how a company with a large number of generic products has structured their PV department. You will see their structure, processes and arrangements in place to comply with regulatory requirements. There will be examples of real life situations and day-to-day PV challenges.

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

14:00-15:30 **Benefit-risk Management in Pharmacovigilance (session + workshop)**
Panos Tsintis
In is a session followed by a workshop, you will learn key concepts in Benefit-risk management in Pharmacovigilance, then you will apply those concepts in a hands-on workshop.

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

15:45-17:00 **Management of the Pharmacovigilance Department – Mid size Pharma company perspective**
Gemma Jimenez Sese
In this presentation you will learn how size and portfolio of products matters when designing a PV department. Presentation focuses on how a Mid pharma company can structure a PV department, establishes processes and arrangements that can be in place to comply with regulatory requirements. There will be examples of real life situations and day-to-day PV challenges.

17:00-17:15 **QUESTIONS AND ANSWERS**

DAY 2
20JUNE 2023

9:00-9:45 **Safety and pharmacovigilance in drug-device combination products**
Joan D'Souza
In this session you will learn specific guidance related to drug-device combination products.

9:45-11:00 **Dear Healthcare Professional Communications**
Calin Lungu
In this session you will learn how to perform Dear Healthcare Professional Communications. On the basis of the GVP Module XV – Safety communication, several aspects of DHCP communications will be reviewed, including format, channels, strategies and considerations derived from National Competent Authority Inspections.

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

11:30-13:00 **Safety in Clinical Studies**
Sarah Daniels
This 1.5 hour presentation will cover both pre and post authorisation safety. It will include the rationale for safety assessment in clinical studies as well as regulatory and practical aspects of safety data collection and interpretation.

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

14:00-14:45 **Experiences from Pharmacovigilance Inspections**
Ivan Arias and Jose A. Ayala Ortiz
In this presentation, Ivan and José will go through their recent experiences and learnings from the QPPV perspective derived from Pharmacovigilance Inspections from EMA performed by the AEMPS.

14:45-15:30 **QPPV oversight**
Ilaria Grisoni
In this presentation, Ilaria will go through methods, tools and strategies for QPPV oversight.

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

15:45-16:30 **PV vendor oversight and management**
Suzanne Nijenhuis
IThis presentation will provide learnings related to vendor oversight and management, including tools and strategies based on hands on experiences on this field.

Closing remark

16:30-17:00 **QUESTIONS AND ANSWERS**

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.

Standard 2 days: **950€**

Standard 1 day: **499€**

*Offers**:*
Early Bird (Until 31th May): 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.
** 21% VAT not included*
*** Offers are non-cumulative, only the most beneficial one would apply*
**** Upon providing a valid SME number*
*****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)

Number of Payment will be made by: ◯ Company ◯ Individual

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PHOTOGRAPHY POLICY

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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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