Best in class pharmacovigilance event

VII EDITION

PHARMACOVIGILANCE TRAINING

Barcelona & Online

12-13 MAY 2026

Join us to learn about the latest Pharmacovigilance updates

PVPharm

10 years at your service

KEY TOPICS

- QPPV tools and day-to-day activities
- PV in global and local context
- News on CIOMS, EMA, EudraVigilance, XEVMPD, EVDAS, Signal Management, CTIS
- Updates on EMA Data Management
- Artificial Intelligence in PV
- Innovation in PV
- Use of RWE data in PV
- Pharmacovigilance Governance
- Business models and integration of PV systems
- Patient safety
- Responsibilities of the MAH with regards to the QPPV and PV
- Pharmacovigilance with innovative, generics and biosimilar products
- Pharmacovigilance in rare diseases
- Contract and agreements in PV
- PSMF
- KPIs in Pharmacovigilance
- RMPs, aRMM measures, Dear Health Care Professional communications
- Experiences from inspections and audits of the MAH, PV local functions, service providers and partners
- Your own input (please send questions in advance to the speakers!)
- Much more...

COURSE OBJECTIVES

This year, the 7th 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.

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.
- Understand what Artificial Intelligence would mean in Pharmacovigilance.
- Learn how other MAHs organize pharmacovigilance activities.
- Stay tuned with the last news from EMA. Understand the implications for MAHs.
- Get updated on CIOMS, EMA, Eudravigilance, EVWeb, XEVMPD, EVDAS, CTIS and PRAC.
- Understand the use of RWE data in PV
- See examples of PV governance models
- See examples of handling the PSMF in a multinational context
- Understand the importance of KPIs in PV
- Get deep understanding about benefit risk evaluation.
- Understand aRMMs, DHCP communications and how to do them.
- Learn about PV inspections and audits.
- 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

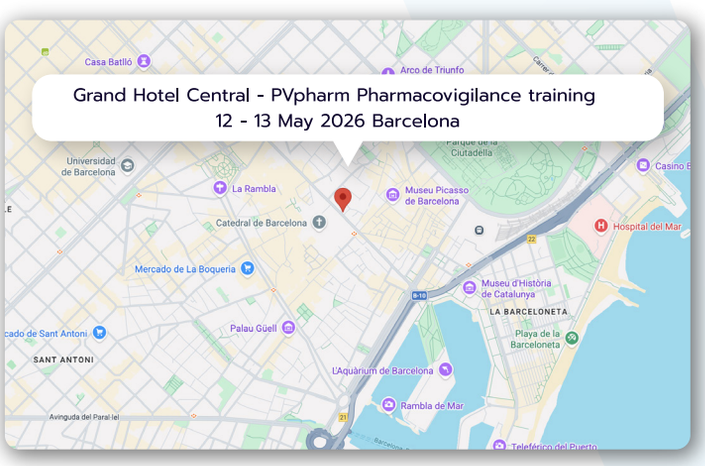
WHAT THE TRAINING INCLUDES

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

WHEN & WHERE

The training will take place next May 12th and 13th in Barcelona, Spain. Join us at the Grand Hotel Central, located in the heart of Barcelona, great location to host this training, to connect with the rest of attendees and to enjoy the city.

www.grandhotelcentral.com



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PVpharm

SPEAKERS

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

CEO, PVpharm

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.

Calin Lungu

CEO, DDCS

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.

Natasha Mihajlovic

Managing director, PV consultant, Nostrapharma

Experienced QPPV, certified lead auditor, and certified trainer with over 28 years in the pharmaceutical consultancy and industry, holding an MSc in pharmacovigilance. Auditing since 2005 and have participated in numerous regulatory pre-inspections and inspections, including those by the EMA, FDA, and various national regulatory authorities such as Swedish, Spanish, French, Irish, German, Croatian, Turkish, and Hungarian, as well as several MHRA inspections. Conducted over 290 audits, accruing more than 670 days of experience auditing headquarters, affiliates, licensing partners, PV processes, computerized system validations, and PV service providers across the EU, US, Middle East, Central and South America, Asia, and Australia. In the past five years, focused primarily on remote and process PV audits, with a particular interest in aRMM/PASS/signal management/compassionate use/artificial intelligence. Additionally, performed over 140 gap analyses of PSMF/PSMF processes. Passionate about training and serve as a Visiting Lecturer at the University of Hertfordshire and the University of Oxford in the UK.

SPEAKERS

Elspeth McIntosh

Senior Pharmacovigilance Consultant, Castle PV

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.

PAV RISHIRAJ

Director, Head of PV & UK QPPV, IPSEN

Visionary and dynamic. A purposeful senior Pharmacovigilance (PV) Leader and safety (GvP) expert with strategic skills, operating at the forefront of the global PV landscape (including UK), with extensive detailed experience spanning over 22 years across multiple functions within Drug Safety including global/local positions, currently employed as Director, Head of Pharmacovigilance. Previous posts include senior management/leadership positions, primarily alongside the QPPV/-VP of PV to ensure strict compliance to GvP (Global, Regional and Local) through robust implementation and oversight of the PV system. At the forefront of PV intelligence and regulation landscapes, a proactive and meticulous leader with local and regional experience to facilitate strong cross-functional collaboration for GvP successes. Strong MHRA/FDA inspection experience and safety strategy implementation from global to regional and local affiliate level. Chairman of the ABPI PV expert network (PEN). Member of the International Society of Pharmacovigilance (ISoP)

Félix Arellano

Global Head of Safety and Risk Management, Roche

Dr Felix Arellano is the Global Head of Safety & Risk Management in Roche, a position he has held for 10 years. Dr Arellano studied medicine at the Universidad Autónoma de Madrid, Spain, and Boston University, United States, followed by postgraduate studies in pharmacoepidemiology at Macgill University, Montreal, Canada and in pharmaceutical medicine (combined Strasbourg, Basel and Freiburg universities). He has in excess of 30 years of experience in Safety in the pharmaceutical industry, having worked in global roles for top 10 pharma in pharmacovigilance of medicines, consumer products, devices and vaccines. In Roche he has overseen the development of Safety to an industry leading team where innovation and compliance are equally important. Dr Arellano has a vision for the future of PV and safety; he believes in building the capabilities needed for new treatment paradigms, patient focus and the use of technology such as AI. Whilst always advocating that the most important element for the future of safety are the people in the team.

SPEAKERS

MICHAEL VON FORSTNER

Managing director, Mesa Laubela Consulting

With over 25 years of experience in the pharmaceutical and biotech industries, Michael is a leader in pharmacovigilance, pharmacoepidemiology, and patient safety. Throughout his career, he has contributed to seven successful MAAs/NDAs/BLAs for innovative medicines and biosimilars by implementing cost-effective risk management systems. Beyond corporate leadership—having managed departments of over 75 FTEs and restored global regulatory compliance—he is a prominent figure in the scientific community, representing the industry at the EMA/PRAC and leading ICH working groups. As a creative entrepreneur and co-founder of startups in AI-driven medicine and digital health, he combines deep technical expertise with a proven track record of building high-performing global teams and driving innovation in drug safety.

MIRCEA CIUCA

Global Head of Safety, Organon

Mircea Ciuca, MD, is an expert in global drug safety and pharmacovigilance with over 20 years of experience, currently serving as the Global Head of Safety at Organon. After graduating from the Carol Davila University of Medicine and Pharmacy, he specialized in emergency medicine and obstetrics-gynecology, spending 12 years in clinical practice and academic teaching before transitioning to the pharmaceutical industry. Throughout his career, he has held senior leadership and QPPV roles at major firms like Vifor Pharma, CSL Behring, and Astellas, complemented by a postgraduate diploma in pharmacovigilance with honors from the University of Hertfordshire.

MARCO SARDELLA

EU-UK QPPV, Adienne

With over twenty years of progressive experience in Pharmacovigilance and Drug Safety, Dr. Marco Sardella is a distinguished leader in global biopharmaceutical safety governance. As Chief Pharmacovigilance Officer and EU-UK Qualified Person for Pharmacovigilance (QPPV), and Head of Global Safety and Pharmacovigilance, he holds executive responsibility for the strategic design, implementation, and continuous oversight of comprehensive Pharmacovigilance and Risk Management Systems in full alignment with international regulatory frameworks. Throughout his career, Dr. Sardella has led pharmacovigilance strategy and execution for numerous therapies targeting rare and ultra-rare diseases, applying deep expertise in both biologic and small-molecule products. His therapeutic experience spans complex and high-risk indications. His portfolio encompasses global Drug Safety Management responsibilities across international clinical trials (Phase I–IV), post-authorization safety studies (PASS), and expanded access programs, including Compassionate Use and Named Patient Programs. Recognized for his strategic vision and collaborative leadership style, Dr. Sardella partners closely with regulatory authorities, executive leadership teams, and cross-functional stakeholders to uphold the highest standards of patient safety and pharmacovigilance governance worldwide. Since 2016, Dr. Sardella serves as the Chairperson of the European Pharmacovigilance Congress.

DAY 1
12 MAY 2026

08:45 - 09:00	**WELCOME AND REGISTRATION**
09:00 - 09:05	**José Ortiz** / CEO, PVpharm Welcome note
09:05 - 09:45	**José Ortiz** / CEO, PVpharm CIOMS 14 - Artificial Intelligence in Pharmacovigilance
09:45 - 10:30	**Natasha Mihajlovic** / Managing director, PV consultant, Nostrapharma AI governance models
10:30 - 11:00	**COFFEE BREAK**
11:00 - 11:45	**Jan Petracek** / CEO, iVigee Beyond Automation: Preventing Complacency in Pharmacovigilance Practice
11:45 - 12:30	**Roundtable with questions to the speakers**
12:30 - 13:45	**LUNCH BREAK**
13:45 - 14:30	**Felix Arellano** / Global Head of Safety and Risk Management, Roche Signal Management, a real case experience
14:30 - 15:15	**Mircea Ciuca** / Global Head of Safety, Organon Fakes, Frauds, and PV: Protecting Patients
15:15 - 15:30	**BREAK**
15:30 - 16:15	**Michael Fortsner** / Managing director, Mesa Laubela Consulting Making recent guidances on risk and benefit-risk management work - how to operationalize GVP XVI, REMS Logic, and CIOMS XII
16:15 - 17:00	**Roundtable with questions to the speakers**

DAY 2
13 MAY 2026

09:00 - 09:45	**Marco Sardella** / EU-UK QPPV, Adienne Pharmacovigilance in rare diseases
09:45 - 10:30	**Elspeth McIntosh** / Senior Pharmacovigilance Consultant, Castle PV Workshop on QPPV Oversight
10:30 - 11:00	**COFFEE BREAK**
11:00 - 11:45	**Jan Petracek** / CEO, iVigee QPPV
11:45 - 12:30	**Roundtable with questions to the speakers**
12:30 - 13:45	**LUNCH BREAK**
13:45 - 14:30	**Natasha Mihajlovic** / Managing director, PV consultant, Nostrapharma Workshop on 'Facelift of PVAs'
14:30 - 15:15	**Calin Lungu** / CEO, DDCS Audits in Pharmacovigilance
15:15 - 15:30	**BREAK**
15:30 - 16:15	**Pav Rishiraj** / Director, Head of PV & UK QPPV, IPSEN Strategic planning in Pharmacovigilance
16:15 - 17:00	**Roundtable with questions to the speakers**
17:00 - 17:10	**José Ortiz** / CEO, PVpharm Final note and closing

REGISTRATION FEES

Includes training and course material in digital format.

Participants that choose to attend the face-to-face option, will receive complementary refreshment breaks and lunches **(limited seats!)**.

Online and interactive training sessions for the remote participants.

Option to join only 1 day (only remote)

Offers: (non-cumulative, only the most beneficial one would apply)

> Standard fee*: 1.400€ 2 days / 799€ 1 day
>
> Early Bird (until 1st April): 20% discount on Standard fee
>
> Reduced fee for SMEs: 10% discount on Standard fee
>
> Register 2 individuals from the same company and receive a 25% discount from the standard fee.
>
> Register 3 individuals from the same company and receive a 30% discount from the standard fee.
>
> *VAT not included.

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 on our website **www.pvpharm.com**
If not possible please email your completed registration form to **trainingservices@pvpharm.com**

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

Full Name (required)

Job Title

Company

Country

Phone

Email (required)

Your message (required)

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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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