PVpharm

PHARMACOVIGILANCE TRAINING

VI Edition Barcelona & Online

12-13 MAY 2025

Join us to learn about the latest Pharmacovigilance updates

www.pvpharm.com

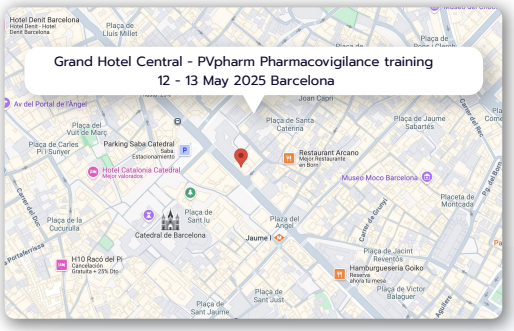
KEYTOPICS

- QPPV tools and day-to-day activities
- PV in global and local context
- News on EMA, EudraVigilance, XEVMPD, EVDAS, Signal Management, CTIS
- Updates on EMA Data Management
- Artificial Intelligence in Pharmacovigilance
- Ethic Considerations of the use of AI
- 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
- Contract and agreements in PV
- PSMF
- KPIs in Pharmacovigilance
- RMPs, aRMM meausures, 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...

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



COURSE OBJECTIVES

This year, the 6th 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-depth 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
- Free lunches, refreshment breaks and networking for face-to-face participants.
- Online and interactive training sessions for the remote participants.

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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.

Ilaria Grisoni

Executive Director, Head of EU/Int PV 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).

Calin Lungu

PV consultant, DDCS CEO

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 Ltd

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 CEO

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.

Shelley Gandhi

Partner at ELIQUENT Life Sciences

Shelley is an experienced and highly motivated pharmacovigilance and risk management expert, with an international reputation in her field, specialising in delivering global safety solutions including safety governance models. Former senior manager at MHRA for over 19 years and represented the UK on EMAs EudraVigilance Expert Working Group. Shelley now supports clients with QPPV, Risk Management, Inspection Readiness and implementation of global PV systems.

Gemma Jiménez Sesé

Senior Director Deputy QPPV, Astra Zeneca

Gemma Jiménez currently holds the position of Deputy EU and UKQPPV at Astrazeneca, based in Barcelona, Spain. Previously, she served as the EUQPPV and Head of Patient Safety at Almirall. With over 20 years of experience in pharmacovigilance, she has taken on roles with increasing responsibility. In pharmacovigilance, she has been involved in a broad scope of activities, encompassing safety in clinical development and support for marketed medicinal products, including small molecules and biologics. Beyond safety, she has led projects in late-phase development and product life-cycle management.

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 Autonóma 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.

José Alberto Ayala Ortiz

PVpharm CEO

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.

SPEAKERS

Gabrielle Amselem

Director, Pharmacovigilance Excellence Expert, AstraZeneca

Gabrielle Amselem (PharmD) is a seasoned pharmacovigilance professional with extensive experience in the QPPV Office. Currently serving as a PV Excellence Expert at AstraZeneca, Gabrielle has led various initiatives aimed at enhancing patient safety, quality, and compliance, with a recent focus on PV agreements, risk management, and regulatory intelligence. Gabrielle has successfully managed the PSMF process for 7 years, has 3 years of experience as Deputy EU/UK QPPV for Alexion, and started their professional career as a Local Safety Officer in France. Gabrielle has been a speaker at several forums and conferences and is committed to advancing the field through continuous collaboration and good practice sharing.

Jørgen Matz

Head of Global Clinical Quality & Pharmacovigilance for InsudPharma

Jørgen Matz, MSc, PhD, PgD is the Head of Global Clinical Quality & Pharmacovigilance for InsudPharma, Madrid, Spain. InsudPharma is a global healthcare company with business units for worldwide manufacturing, development, and marketing of branded, generic, and biotechnological products. Jørgen Matz has several years of experience from working with drug safety & pharmacovigilance. He has a science background as an experimental pharmacologist. In recent years he focussed on implementing pharmacovigilance systems, automatizations, and drug safety platforms that benefit functions in R&D, Clinical QA and Global Pharmacovigilance.

Hervé Dhellot

Global pharmacovigilance Head, QPPV, Pharma Mar

Hervé Dhellot, MD, MSc, began his career in as physician in hospital before joining the pharmaceutical industry in 2000. Since then, Hervé has gained 25 years' experience in Pharmacovigilance. He worked for Roche, Bouchara Recordati at Affiliate level in and, Sanofi-Aventis and Pharma Mar at Headquarters level. For the last 13 years onward, Hervé has hold the positions of Global pharmacovigilance Head and Qualified Person for Pharmacoviglance in Pharma Mar.

Angela van der Salm

Director Pharmacovigilance, Managing partner DADA

Angela has almost 20 years experience in PV with 15 years of functioning as a (deputy) QPPV. With her company, she provides customized pharmacovigilance support, including QPPV provision and responsibility for the clients' pharmacovigilance systems, as set-up within DADA's PV department. After her PhD in 2005, she started her career in pharmacovigilance at a generic pharmaceutical company and in 2008, she joined an innovator to gain experience in PV during the different mergers taking place at that time. In 2010, she was invited by DADA Consultancy to start up a department of PV consultants to take on global and local responsibilities from clients in need of PV support. Her personal interests lie with Compliance management and auditing, as well as Risk Management and Medication Errors, and she recently obtained a MSc in Clinical Epidemiology.

Omar Aimer

President North American Chapter of ISoP

Omar is a Pharmacovigilance SME based in Montreal, Canada. He is an Executive Committee member and Treasurer of the International Society of Pharmacovigilance (ISoP), North American chapter President and serves as a Leader of the Medical Device Safety – Special Interest Group. He previously held leadership roles in pharmaceutical companies in Algeria, France and Canada. He holds a Degree in Pharmacy and PhD in Pharmacology from Algiers University, Algeria and a Master in Pharmacovigilance and Drug Safety from Paris Descartes University, France. Omar has presented in multiple scientific forums with interest in new technologies, medical device safety and the improvement of pharmacovigilance around the world

CHAIRPERSONS

Nuria Cabello

PV Manager and QPPV of Farmaprojects SAU (Polpharma Group)

Nuria is currently PV Manager and QPPV of Farmaprojects SAU (Polpharma Group). She is also member of the Spanish Industry Pharmacists Association (AEFI) acting as Pharmacovigilance Delegate in Catalan section. She has been working over 12 years in pharmacovigilance in both service provider and pharmaceutical industry managing very different variety of products and therefore PV systems.

Julia Vera

Pharmacovigilance & Safety Director, Evidenze Group

Holding a degree in Pharmacy from the University of Valencia and a Master's in Clinical Trials Management and Monitoring, Julia Vera has over 15 years of experience in the pharmaceutical field. She has held senior positions in various international CROs, specializing in clinical safety management, pharmacovigilance, and regulatory compliance across multiple therapeutic areas.

Beyond her professional career, Julia is an active member of the Spanish Association of Industrial Pharmacists (AEFI) and currently serves as Vice President of its Catalonia section, participating in working groups on pharmacovigilance and clinical research. She has also contributed to specialized publications and has been a speaker in training programs on clinical trial safety.

José Alberto Ayala Ortiz

PVpharm CEO

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
12 MAY 2025

8:45-9:00 WELCOME AND REGISTRATION

9:00-9:05 **José Ortiz**
PV consultant, QPPV, PVpharm CEO
Welcome note

9:05-9:45 **Calin Lungu**
PV consultant, DDCS CEO
Updates on EMA IT systems and master data management

9:45-10:30 **Jan Petracek**
PV consultant, iVigee CEO
AI in pharmacovigilance, what is possible today?

10:30-11:00 COFFEE BREAK

11:00-11:40 **Omar Aimer**
President North American chapter of ISoP
AI in pharmacovigilance, practical examples and ethic considerations

11:40-12:20 **José Ortiz**
PV consultant, QPPV, PVpharm CEO
Use of AI in signal detection

12:20-13:00 **Roundtable with questions to the speakers**
Moderated by José Ortiz, PV consultant, QPPV, PVpharm CEO

13:00-14:00 LUNCH BREAK

14:00-14:40 **Felix Arellano**
Global Head of Safety and Risk Management, Roche
Innovation in PV

14:40-15:20 **Ilaria Grisoni**
Executive Director, Head of EU/International PV & Global Risk Management and EEA, Gentium Srl, A Jazz Pharmaceuticals Company, Italy
Use of RWE data in pharmacovigilance

15:20-15:40 BREAK

15:40-16:20 **Shelley Gandhi**
Partner at ELIQUENT Life Sciences
QPPV tools and perspectives for the integration of AI in Pharmacovigilance

16:20-17:00 **Roundtable with questions to the speakers**
Moderated by Nuria Cabello, PV Manager & QPPV, Farmaprojects SAU

DAY 2
13 MAY 2025

9:00-9:45 **Jorgen Matz**
Head, Global Clinical Quality & Pharmacovigilance, Insud Pharma
Building a Robust Pharmacovigilance Framework: Governance Insights for a Growing Spanish Pharmaceutical Company

09:45-10:30 **Hervé Dhellot**
QPPV and Global Pharmacovigilance Head , Pharmamar
Responsibilities of the MAH regarding the QPPV: digging into the role of the MAH in ensuring that the QPPV establishes and maintains the pharmacovigilance system.

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

11:00-11:40 **Gemma Jiménez**
Senior Director Deputy QPPV, Astra Zeneca
One size doesn't fit all: Tailoring PV governance

11:40-12:20 **Elspeth McIntosh**
Senior Pharmacovigilance Consultant, Castle PV
UK QPPV updates

12:20-13:00 **Roundtable with questions to the speakers**
Moderated by Julia Vera, Pharmacovigilance & Safety Director at Evidenze Group

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

14:00-14:40 **Gabrielle Amselem**
Alexion, AstraZeneca Rare Disease, France. Dir, Pharmacovigilance Excellence Expert
PV Contracts and Agreements - aligning safety and partnership

14:40-15:20 **Natasha Mihajlovic**
Managing director, PV consultant, NostraPharma Ltd
PSMF Breaking Bad – challenges, pitfalls and what we can do better

15:20-15:40 **BREAK**

15:40-16:20 **Angela van der Salm**
Director Pharmacovigilance, Managing partner DADA
KPIs in Pharmacovigilance

16:20-17:00 **Roundtable with questions to the speakers**
Moderated by José Ortiz, PV consultant, QPPV, PVpharm CEO

17:00-17:10 **José Ortiz**
PV consultant, QPPV, PVpharm CEO
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

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

Standard fee*: 1.200€ 2 days / 699€ 1 day

Early Bird (until 1st April): 960€ 2 days / 559€ 1 day

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 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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Photography policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by PVpharm in promotional material, publications, and website and waive any and all rights including but not limited to compensations or ownership. Please read about our privacy policy at https://www.pvpharm.com/privacy-policy

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.

PVPharm

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