PVpharm

Pharmacovigilance services for the Pharmaceutical Industry

PHARMACOVIGILANCE TRAINING

II Edition

MADRID

9-10 MAY
2019

Join us to learn about the latest Pharmacovigilance updates

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www.pvpharm.com

KEY TOPICS

- EU-QPPV perspective
- Organizational aspects in Pharmacovigilance: the PV department
- Audits and Inspections in PV
- Auditing of the QPPV function
- Audit of PSURs and interfaces in the company
- Audit of computerised systems in Pharmacovigilance
- Data protection, GDPR in Pharmacovigilance
- EVDAS: Signal Detection in EudraVigilance
- EVDAS: medical evaluation
- Sources of information in pharmacovigilance
- Regulator perspective, international experiences
- Practical examples and activities
- Questions and answers and more…

WHEN AND WHERE

The training will take place next **May 9th and 10th in Madrid**, Spain.
Join us at the **Hotel Emperador**, located in Madrid city center, great location to host this training, to connect with the rest of attendees and to enjoy the city.
www.emperadorhotel.com

COURSE OBJETIVES

This year we will focus on different areas, but always from the perspective of the QPPV. We will talk about how a PV department is organized, the role of the QPPV and how this function is audited. A Pharmacovigilance audit is a very important activity to carry out in a pharmaceutical company. Thanks to audits you can detect the risks existing in the system and set up priorities to ensure company regulations compliance and protection. Consequently, by auditing, the company avoids any inspection problem. Moreover, apart from the QPPV audit we will have the opportunity to learn about the audit of the process of PSUR production and submission and, also, about the auditing of computerised systems in Pharmacovigilance.

This pharmacovigilance training will also cover personal data protection issues in Pharmacovigilance, we will talk about the GDPR from a lawyer perspective.

We will also be talking about the latest updates in the use of EVDAS for signal detection in pharmacovigilance, with practical examples of medical evaluation in signal management, focussing also on the issues most frequently encountered.

Furthermore, our course will treat other different subject such as the international context of pharmacovigilance, and sources of information in pharmacovigilance, in order to document signal detection, ICSRs, PSURs, Referrals and more, presenting practical situations which may impact on daily activities.

The course will be delivered by experienced trainers in the field who know the most critical aspects affecting PV employees firsthand. Throughout the training sessions, practical examples and frequently asked questions will be addressed through a rigorous and practical approach.

ABOUT THE TRAINERS

MARIANO MADURGA

Mariano Madurga is a pharmacist, with training in Public Health, Pharmacoepidemiology and Pharmacovigilance. The last 30 years have been dedicated to information on medicines, development of databases and pharmacovigilance systems, along with teaching and research. Since 1986 he has been an official of the Ministry of Health of Spain. In the AEMPS has developed and coordinated the Spanish Pharmacovigilance System (SEFV), unique model in the EU environment, until his retirement. His experience has served as a model for the network of PV in Central America, the FACEDRA system. He is currently a Pharmacovigilance and Expert Consultant for PAHO and Reviewer in the Signal Review Panel of UMC, WHO

JOSÉ ALBERTO AYALA ORTIZ

José Alberto Ayala Ortiz (M.Sc. Pharm. and M.Sc. IT) has been working 15 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, 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, were he is the CEO.

CALIN LUNGU

Dr. Lungu has worked for more than 20 years in drug development, clinical research, pharmacovigilance and quality assurance. He has done over 140 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.

ALBERT GARCÍA RIEROLA

Bachelor of Sciences in Pharmacy at the University of Barcelona. He is currently the EU-Qualified person responsible for pharmacovigilance (QPPV) at Ferrer Internacional, a Spanish private pharmaceutical company. He joined Ferrer in 2008, where he has gained experienced in different areas such as regulatory affairs and price and reimbursement, although his main focus has been in the pharmacovigilance field. He was appointed Deputy QPPV in 2009, and promoted to QPPV in 2013. He has been responsible for building a pharmacovigilance system for the company, not only at European level but also at worldwide level.

MAITE VÁZQUEZ

Maite Vázquez Calo is economist and lawyer, with training in Biotechnology and Pharma Law.
As partner, she leads DA Lawyers Life Science practice. The last 20 years she has been advising companies in pharma and bio industry in regulatory, contracts, corporate and compliance matters.
She is the secretary of the Board of the Spanish Biotechnology Association (ASEBIO) and legal advisor in the Pharma and Health group of the Bar Association of Madrd (ICAM)

DAY 1
9 MAY 2019

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

9:00-9:30 Introduction and overview of the agenda
Jose Alberto Ayala

9:30-11:00 Pharmacovigilance international context, experience in implementation of national pharmacovigilance systems
Mariano Madurga

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

11:30-13:00 The pharmacovigilance department in a MAH, QPPV persective (I)
Albert García

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

14:00-15:30 The pharmacovigilance department in a MAH, QPPV persective (II)
Albert García

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

16:00-16:30 Auditing the QPPV function
Calin Lungu

16:30-17:00 Audit of PSURs and interfaces in the company in the process of PSUR production and submission
Calin Lungu

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

DAY 2
10 MAY 2019

9:00-10:30 GDPR in pharmacovigilance
Maite Vázquez

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

11:30-12:15 EVDAS and signal management
Jose Alberto Ayala

12:15-13:00 Medical evaluation in signal management and issues frequentely encountered
Calin Lungu

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

14:00-15:30 Sources of information in PV (documenting ICSRs, PSURs, Referals)
Mariano Madurga

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

16:00-17:00 Audits of computerised systems in PV
Calin Lungu

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

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REGISTRATION FEES

Registration fee includes two days training, refreshment breaks, lunches and training course material in digital format.

- Standard: **850€**
- Reduced fee- SME **: **750€**
- Early Bird (Until 9th April): **700 €**

Register 2 individuals from the same company and receive a 20% discount from the standar fee.

* 21% VAT not included
** Upon providing a valid SME number
*** Special fees for University students/unemployed (upon presentation of documentation): info at info@pvpharm.com

REGISTRATION FORM

Please complete with capital letters. Email your completed registration from to *info@pvpharm.com* and you will receive payment instructions.

○ Prof ○ Dr ○ Ms ○ Mrs

Last name | First name

Company | Job Title

Address

Postal code | City | Country

Telephone | Email (required for confirmation)

○ I accept the terms, conditions and cancellation policy.
○ I declare that i have read, understood, accept and give consent to the terms stated at the privacy policy in line with European General Data Protection Regulation (GDPR) (EU) 2016/679 avaliable at httpp://www.pvpharm.com/privacy-policy

SEND **PRINT**

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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 no 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 cancelled or postponed, cost incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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