



## **13<sup>th</sup> Romanian Pharmacovigilance Workshop**

**EMA news, XEVMPD, PMS, PSMF, EU and extra-EU PV inspections, GVP updates, challenges in pharmacovigilance, inspections and national specific requirements for Romanian MAHs, QPPV oversight, case studies and more...**

**Bucharest, 21 – 23 October 2026**

This 13<sup>th</sup> pharmacovigilance workshop aims to present updates and practical aspects, with impact on daily activities and regulatory compliance. A more interactive setting, with practical exercises is organized. If time allows, bonus presentations can be made.

**Depending on registrations from different countries, this event may be held as a hybrid event.**

### **Faculty**

- Calin LUNGU, MD, DDCS S.A., Luxemburg
- Mircea CIUCA, MD, Organon, Switzerland
- Marco SARDELLA, PharmD, ADIENNE, Italy
- Jose ORTIZ, M.Sc.Pharm, PVpharm, Spain
- Lecturer from Romanian NCA (to be announced)



# Agenda

Day 1

**Wednesday 21 October  
2026**

## **Morning**

08:30 – 09:00

Welcome and registration

9:00 – 09:15

Introduction and overview of the agenda

09:15 – 10:15

Global PSMF Management  
(Marco SARDELLA)

10:15 – 10:45

Coffee break

10:45 – 12:00

Real life experiences of 2026 GVP inspections (Marco SARDELLA)

12:00 – 12:30

Questions and Answers

12:30 – 13:45

Lunch Break

## **Afternoon**

14:00 – 14:45

QPPV Oversight in Practice  
(Marco SARDELLA)

14:45 – 15:30

Interactive Discussion on PSMF and QPPV Oversight (Q&A)  
(Marco SARDELLA – Calin LUNGU)

15:30 – 16:00

Coffee break

16:00 – 16:45

Recent trends in pharmacovigilance audits and inspections (Calin LUNGU)

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



## Thursday 22 October 2026

### Morning

9:00 – 10:15

Population specific GVP guidance with hands-on exercises (Mircea CIUCA)

10:15 – 10:40

Coffee break

10:40 – 12:00

EU Pharmacovigilance legislation updates (Calin LUNGU)

12:00 – 12:30

PV in global and local context in the framework of the EMA network strategy (Jose ORTIZ)

12:30 – 13:30

Lunch Break

### Afternoon

13:30 – 14:15

Interactive Discussion on GVP Inspections (Q&A) (Marco SARDELLA – Calin LUNGU)

14:15 – 15:00

Updates to GVP for signal and risk management (Mircea CIUCA)

15:00 – 15:40

Coffee break

15:40 – 16:15

Hands-on case study on EVDAS (Calin Lungu and Mircea CIUCA)

16:15 – 16:45

Updates on XEVMPD and PMS (Calin LUNGU)

16:45 – 17:00

Questions and Answers

17:00

End of Day 2



## Friday 23 October 2026

09:00 – 10:00

Challenges in pharmacovigilance, inspections and national specific requirements for Romanian MAHs (Lecturer from the Romanian NCA to be announced)

10:00 – 10:30

Questions and answers about previous presentation (Lecturer from the Romanian NCA to be announced)

10:30 – 11:00

Coffee Break

11:00 – 12:00

Use of artificial intelligence in pharmacovigilance (Calin LUNGU and Mircea CIUCA)

12:00 – 13:00

From scientific evidence to regulatory action: connecting risk detection with strategic management in pharmacovigilance (Jose ORTIZ)

13:00

End of the workshop

The workshop will be held at:

**Hotel Capital Plaza**  
**Bd. Iancu de Hunedoara, nr 54,**  
**sector 1, 011745 București,**  
**Romania**

The registration form will be available in due course.

Please contact Alexandru Popescu ([alexandru.popescu@businessstravel.ro](mailto:alexandru.popescu@businessstravel.ro)) for any questions regarding this course and if you like to register.

Online registration at <https://pharmacovigilance.ro>



The above agenda can be modified in short notice due to availability of speakers. It is recommended to bring a laptop for the best experience with practical case studies.