



12th Romanian Pharmacovigilance Workshop

EMA news, PMS, drug shortages and counterfeits, , Real-World Data in Action: Strengthening Regulatory Safety Decisions , case studies and more...

Bucharest, 27 – 29 October 2025

This 12th 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., Luxembourg
- Mircea CIUCA, MD, Organon, Switzerland
- Marco SARDELLA, PharmD, Adienne, Italy
- Prof. John Borg, Malta Medicines Agency, Malta



Agenda

Day 1

Monday 27 October 2025

Morning

08:30 – 09:00

Welcome and registration

9:00 – 09:15

Introduction and overview of the agenda

09:15 – 10:00

The importance of monitoring the manufacturing as an important task of pharmacovigilance (Marco SARDELLA)

10:15 – 10:45

Coffee break

10:45 – 12:00

Benefit/Risk evaluation: from CTD Module 5 to CTD Module 2.7 (Clinical Summaries), CTD Module 2.5 (Clinical overview) (Marco SARDELLA)

12:00 – 12:30

Questions and Answers

12:30 – 13:45

Lunch Break

Afternoon

14:00 – 14:45

SmPC Section 4.8 Undesirable Effects including examples of MedDRA groupings

14:45 – 15:30

Exercise on MedDRA grouping for SmPC purposes (Marco SARDELLA – Calin LUNGU)

15:30 – 16:00

Coffee break

16:00 – 16:45

Exercise: identification of MedDRA terms indicative of potential product issues/counterfailing (Marco SARDELLA – Calin LUNGU)

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



Agenda

Day 2

Afternoon

Tuesday 28 October 2025

Morning

9:00 – 10:15
Real-World Data in Action:
Strengthening Regulatory Safety
Decisions (Mircea CIUCA)

10:15 – 10:40
Coffee break

10:40 – 12:00
EMA news
PMS Part 1 (Calin LUNGU)

12:00 – 12:30
Questions and Answers

12:30 – 13:30
Lunch Break

13:30 – 14:15
Evaluation of safety in a marketing
authorisation application (John Borg)

14:15 – 15:00
How Drug Shortages and Counterfeits
Threaten Patient Safety (Mircea CIUCA)

15:00 – 15:40
Coffee break

15:40 – 16:15
Unmasking the threat - a hands-on
case study on drug counterfeiting
(Calin LUNGU and Mircea CIUCA)

16:15 – 16:45
Data Quality of Individual Case Safety
Reports – Dos and don'ts (Calin
LUNGU)

16:45 – 17:00
Questions and Answers

17:00
End of Day 2



Wednesday 29 October 2025

09:00 – 10:15

Case study in groups: Responding to inspection findings related to Quality Management System: QC/QA management – SOP – Training (Calin LUNGU and Mircea CIUCA)

10:15 – 10:45

Discussion of the case studies (Calin LUNGU and Mircea CIUCA)

10:45 – 11:15

Coffee Break

11:15 – 12:00

PMS Part 2 (Calin LUNGU)

12:00 – 13:00

Questions and Answers
Feedback and suggestions for the next workshop

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) for any questions regarding this course and if you like to register.

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

