



## 11<sup>th</sup> Romanian Pharmacovigilance Workshop

**EMA news, assessing PSURs by NCAs, artificial intelligence in pharmacovigilance, ISO IDMP, pharmacovigilance in the context of rare disease, case studies and more...**

**Bucharest, 2 – 4 October 2024**

This 11<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., Luxembourg
- Mircea CIUCA, MD, Organon, Switzerland
- Marco SARDELLA, PharmD, Adienne, Italy
- Prof. John Borg, Malta Medicines Agency, Malta



# Agenda

Day 1

## Wednesday 2 October 2024

### Morning

08:30 – 09:00

Welcome and registration

9:00 – 09:15

Introduction and overview of the agenda

09:15 – 10:00

PBRER assessment methods and practices at the EMA – A practical approach (John BORG)

10:15 – 10:45

Coffee break

10:45 – 12:00

EMA news  
ISO IDMP Part 1 (Calin LUNGU)

12:00 – 12:30

Questions and Answers

12:30 – 13:45

Lunch Break

### Afternoon

14:00 – 14:45

Artificial Intelligence (AI) in pharmacovigilance (Mircea CIUCA)

14:45 – 15:30

Pharmacovigilance for biological medicinal products (Calin LUNGU)

15:30 – 16:00

Coffee break

16:00 – 16:45

ISO IDMP Part 2 (Calin LUNGU)

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



# Agenda

## Day 2

### Thursday 3 October 2024

#### Morning

9:00 – 10:15

Case study 1 in groups: Signal management (Calin LUNGU and Marco SARDELLA)

10:15 – 10:40

Coffee break

10:40 – 11:20

Discussion of the case study (Calin LUNGU and Marco SARDELLA)

11:20 – 12:00

Pharmacovigilance in the context of rare disease (Marco SARDELLA)

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

#### Afternoon

13:30 – 14:15

Pharmacovigilance system audits (Calin LUNGU)

14:15 – 15:00

Global Pharmacovigilance Inspections (Marco SARDELLA)

15:00 – 15:40

Coffee break

15:40 – 16:15

Case study 2: PBRER assessment (Calin LUNGU and Marco SARDELLA)

16:15 – 16:45

Discussion of the case study (Calin LUNGU and Marco SARDELLA)

16:45 – 17:00

Questions and Answers

17:00

End of Day 2



## Friday 4 October 2024

09:00 – 10:15

Case study in groups: Responding to inspection findings related to quality assurance audits (Calin LUNGU)

10:15 – 10:45

Discussion of the case study (Calin LUNGU)

10:45 – 11:15

Coffee Break

11:15 – 12:00

Group polls

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

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

