



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

**EMA computer systems news, IRIS, creating PSMFs, PSURs, RMPs, SPOR and more...**

**Bucharest, 25 – 27 October 2023**

This 10<sup>th</sup> pharmacovigilance workshop aims to present practical aspects, with impact on daily activities and regulatory compliance. A more interactive setting, with polls and case studies 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



# Agenda

Day 1

**Wednesday 25 October  
2023**

## **Morning**

08:30 – 09:00

Welcome and registration

9:00 – 09:15

Introduction and overview of the agenda

09:15 – 10:00

Preparing a Pharmacovigilance System Master File

10:15 – 10:40

Coffee break

10:40 – 11:20

Preparing a Periodic Safety Update Report

11:20 – 12:00

ISO IDMP status updates

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

Afternoon

13:30 – 14:15

Data quality of individual case safety reports (ICSRs)

14:15 – 15:00

IRIS portal

15:00 – 15:40

Coffee break

15:40 – 16:15

XEVMPD refresher, changes, issues and solutions

16:15 – 16:45

Preparing a Risk Management Plan

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



## Thursday 26 October 2022

### Morning

9:00 – 10:15

Case study 1 in groups:  
Responding to inspection findings  
related to the case management

10:15 – 10:40

Coffee break

10:40 – 11:20

Discussion of the case study

11:20 – 12:00

Preparing a Dear Healthcare  
Professional Communication  
(DHPC)

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

### Afternoon

13:30 – 14:15

Computerised system audits

14:15 – 15:00

Pharmacovigilance                      Inspections  
(metrics and common findings)

15:00 – 15:40

Coffee break

15:40 – 16:15

Case study 2 in groups: Responding to  
inspection findings related to the  
Quality Management System

16:15 – 16:45

Discussion of the case study

16:45 – 17:00

Questions and Answers

17:00

End of Day 2



# Agenda

Day 3

## Friday 27 October 2023

09:00 – 09:45

Substance, Product, Organisation and Referentials Management Services (SPOR) news

09:45 – 10:30

EMA account, service desk, EudraVigilance news

10:30 – 11:10

Coffee Break

11:10 – 11:50

Group polls

11:50 – 12:15

Questions and Answers

13:00

End of the workshop

The workshop will be held at:

**Crowne Plaza Hotel,  
Bulevardul Poligrafiei 1,  
sector 1, Bucharest,  
Romania**

The registration form will be available in due course.

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