



6th Romanian Pharmacovigilance Workshop

EudraVigilance news, Signal detection, pharmacovigilance inspections and audits, risk management plans and more...

Bucharest, 11 – 13 September 2019

Since 22 November 2017, we have witnessed a year of many changes, regulatory as well as technical. These changes have far reaching implications for both regulators and industry. This 6th pharmacovigilance workshop aims to present practical aspects, with impact on daily activities and regulatory compliance.

Faculty

- Calin LUNGU, MD, DDCS S.A., Luxembourg



Agenda

Day 1

Wednesday 11 September 2019

Morning

08:30 – 09:00

Welcome and registration

9:30 – 09:15

Introduction and overview of the agenda

09:15 – 10:00

EudraVigilance news

10:15 – 10:40

Coffee break

10:40 – 11:20

EVDAS main concepts and tools for MAHs, experience from the pilot phase

11:20 – 12:00

User interaction with the EMA service desk

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

Afternoon

13:30 – 14:15

EU Risk management plans (Part 1)

14:15 – 15:00

EU Risk management plans (Part 2)

15:00 – 15:40

Coffee break

15:40 – 16:15

XEVMPD refresher, issues and solutions (Part 1)

16:15 – 16:45

XEVMPD refresher, issues and solutions (Part 2)

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



Thursday 12 September 2019

Morning

9:00 – 10:15

Pharmacovigilance inspections – common findings and metrics

10:15 – 10:40

Coffee break

10:40 – 11:20

Patient registries

11:20 – 12:00

Referral procedures

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

Afternoon

13:30 – 14:15

EMA's committees for human medicinal products

14:15 – 15:00

The handling of safety signals from a regulatory perspective

15:00 – 15:40

Coffee break

15:40 – 16:15

Pharmacovigilance audits of contract partners and service providers

16:15 – 16:45

Pharmacovigilance audits of the signal detection process

16:45 – 17:00

Questions and Answers

17:00

End of Day 2



Agenda

Day 3

Friday 13 September 2019

09:00 – 09:45

SPOR and the interface with the EMA unique account and EudraVigilance registration

09:45 – 10:30

Case study: registration of a new QPPV with EudraVigilance in the new EMA unique account and SPOR

10:30 – 11:10

Coffee Break

11:10 – 11:50

ICSR downloads: common issues, common mistakes and consequences in signal detection

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