9th Romanian Pharmacovigilance Workshop

EudraVigilance news, Signal detection, PASS, PAES, Advanced therapy medicinal products, inspections and audits, SPOR and more...

Bucharest, 2 – 4 November 2022

We have witnessed a year of many changes, regulatory as well as technical. This 9th pharmacovigilance workshop aims to present practical aspects, with impact on daily activities and regulatory compliance. Unprecedented changes have also occurred to pharmacovigilance activities due the Covid-19 pandemic.

Due to possible travel or meeting restrictions that might be in place, this workshop may be held online with the same agenda.

Faculty

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

Agenda

Day 1

Morning

08:30 – 09:00
Welcome and registration

9:30 – 09:15
Introduction and overview of the agenda

09:15 – 10:00
Post-Authorisation Safety Studies

10:15 – 10:40
Coffee break

10:40 – 11:20
Post-Authorisation Efficacy Studies

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
EU ICSR Implementation Guide Rev.2

14:15 – 15:00
Medication errors

15:00 – 15:40
Coffee break

15:40 – 16:15
XEVMPD refresher, changes, issues and solutions

16:15 – 16:45
Medicines under additional monitoring

16:45 – 17:00
Questions and Answers

17:00
End of Day 1

Agenda

Day 2

Thursday 3 November 2022

Morning

9:00 – 10:15
Clinical Trials Information System (CTIS) Part 1

10:15 – 10:40
Coffee break

10:40 – 11:20
Clinical Trials Information System (CTIS) Part 2

11:20 – 12:00
Advanced Therapy Medicinal Products (ATMP)

12:00 – 12:30
Questions and Answers

12:30 – 13:30
Lunch Break

Afternoon

13:30 – 14:15
Pharmacovigilance quality systems

14:15 – 15:00
Pharmacovigilance Inspections

15:00 – 15:40
Coffee break

15:40 – 16:15
Preparing a pharmacovigilance inspection by the Marketing Authorisation Holders

16:15 – 16:45
Pharmacovigilance audits of service providers and partners

16:45 – 17:00
Questions and Answers

17:00
End of Day 2

Agenda

Day 3

Friday 4 November 2022

09:00 – 09:45
SPOR and the interface with the EMA unique account and other EMA systems

09:45 – 10:30
EMA account and service desk news

10:30 – 11:10
Coffee Break

11:10 – 11:50
Case study: XEVMPD updates following a company acquisition, what needs to be done

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.