8th Romanian Pharmacovigilance Workshop

EudraVigilance news, Signal detection, Brexit, Clinical Trials Information Systems, inspections and audits, ISO IDMP implementation and more...

Bucharest, 16 - 18 November 2021

Since the beginning of the Covid-19 pandemic, we have witnessed a year of many changes, regulatory as well as technical. This 8th pharmacovigilance workshop aims to present practical aspects, with impact on daily activities and regulatory compliance.

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

Tuesday 16 November 2021

Morning

08:30 – 09:00
Welcome and registration

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

09:15 – 10:00
EudraVigilance news, EVWEB evolutions, XCOMP activation and changess

10:15 – 10:40
Coffee break

10:40 – 11:20
EVDAS main concepts and tools for MAHs, experience from the pilot phase, use in special populations and orphan drugs

11:20 – 12:00
The EMA SME office

12:00 – 12:30
Questions and Answers

12:30 – 13:30
Lunch Break

Afternoon

13:30 – 14:15
EMA unique account: roles and management

14:15 – 15:00
PRIority Medicines scheme (PRIME)

15:00 – 15:40
Coffee break

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

16:15 – 16:45
Brexit: EU and MHRA requirements

16:45 – 17:00
Questions and Answers

17:00
End of Day 1

Agenda

Day 2

Wednesday 17 November 2021

Morning

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

10:15 – 10:40
Coffee break

10:40 – 11:20
CTIS Part 2

11:20 – 12:00
Educational materials: examples of comments from NCAs

12:00 – 12:30
Questions and Answers

12:30 – 13:30
Lunch Break

Afternoon

13:30 – 14:15
Status of ISO IDMP standards implementation

14:15 – 15:00
Safety communication, DHCP communications, an NCA perspective

15:00 – 15:40
Coffee break

15:40 – 16:15
Pharmacovigilance audits of service providers

16:15 – 16:45
Remote pharmacovigilance audits and audits of commercial partners

16:45 – 17:00
Questions and Answers

17:00
End of Day 2

Agenda

Day 3

09:00 – 09:45
SPOR explained, current and future interfaces

09:45 – 10:30
Case study: answering to findings from a pharmacovigilance inspection

10:30 – 11:10
Coffee Break

11:10 – 11:50
Preparing for audits and inspections, including remote events

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 is available at the contact below.

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