



5th Romanian Pharmacovigilance Workshop

EudraVigilance changes, EMA unique user account, Signal detection, daily use of EVDAS eRMRs, updating procedures for signal detection, pharmacovigilance audits and more...

Bucharest, 24 – 25 October 2018

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 5th pharmacovigilance workshop aims to present practical aspects, with impact on daily activities and regulatory compliance.

Faculty

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



Thursday 24 October 2018

Morning

08:30 – 09:00

Welcome and registration

9:30 – 09:15

Introduction and overview of the agenda

09:15 – 10:00

EudraVigilance overview of changes since 22 November 2017

10:15 – 10:40

Coffee break

10:40 – 11:20

EVWEB 8 and its evolution since the initial version

11:20 – 12:00

EVDAS main concepts and tools for MAHs

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

Afternoon

13:30 – 14:15

Concepts of quantitative signal detection in EudraVigilance

14:15 – 15:00

The use of electronic reaction monitoring reports (eRMRs)

15:00 – 15:40

Coffee break

15:40 – 16:15

Medical evaluation of eRMRs

16:15 – 16:45

EudraVigilance Registration EMA unique user account

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



Agenda

Day 2

Friday 25 October 2018

09:00 – 09:45

Integrating the use of EVDAS in signal management processes

09:45 – 10:30

Traceability of EVDAS activities and updating signal management standard operating procedures

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

12:15 – 13:15

Lunch Break

13:15 – 14:30

Pharmacovigilance audits – Part 1

14:30 – 14:45

Coffee Break

14:45 – 15:45

Pharmacovigilance audits – Part 2

15:45 – 16:15

Questions and Answers

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