



3rd Romanian Pharmacovigilance Workshop

MedDRA 27th SOC, Medication errors, EudraVigilance changes, Medical Monitoring Services, Signal detection, ISO standards and more...

Bucharest, 12 – 13 May 2016

2015 has been a year of many changes, regulatory as well as technical. 2016 and beyond will bring more updates and requirements with far reaching implications for both regulators and industry. This 3rd 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

Thursday 12th May 2016

Morning

08:30 – 09:00

Welcome and registration

9:30 – 09:15

Introduction and overview of the agenda

09:15 – 10:00

EudraVigilance 2016 and beyond

10:15 – 10:40

Coffee break

10:40 – 11:20

MedDRA Version 19.0

11:20 – 12:00

MedDRA SOC “Product Issues”

12:00 – 12:30

Questions and Answers

12:30 – 13:30

Lunch Break

Afternoon

13:30 – 14:15

GVP XVI – Addendum I
“Educational Materials”

14:15 – 15:00

EMA Guidance on Medication Errors

15:00 – 15:40

Coffee break

15:40 – 16:15

EudraVigilance Stakeholder Change
Management Plan

16:15 – 16:45

EudraVigilance Registration and
Training Updates

16:45 – 17:00

Questions and Answers

17:00

End of Day 1



Agenda

Day 2

Friday 13th May 2016

09:00 – 09:45
EudraVigilance Data Access Policy

09:45 – 10:30
EMA Medical Literature Monitoring Services

10:30 – 11:10
Coffee Break

11:10 – 11:50
Signal Detection – News for MAHs

11:50 – 12:15
Questions and Answers

12:15 – 13:15
Lunch Break

13:15 – 14:30
The ISO ICSR (ICH E2B(R3))

14:30 – 14:45
Coffee Break

14:45 – 15:45
XEVMPD updates

15:45 – 16:15
Questions and Answers

16:15 End of Day 2

The workshop will be held at:

**Novotel Hotel, Calea
Victoriei 37B, sector 1,
Bucharest, Romania**

The registration form will be available in due course.

Please contact Madalina Nedelciu (madalina.nedelciu@businessstravel.ro) for any questions regarding this course and if you like to register