OVERVIEW

This course will teach basic concepts of signal detection and signal management and how to apply them within the participants’ functions, including the data mining techniques for large volume ADR data analysis, relevant EMA guidelines as well as a future outlook.

The entire course is updated in line with the latest guidelines on EU Good Pharmacovigilance Practices (GVP): Module IX – Signal management, Commission Implementing Regulation (EU) No. 520/2012, and CIOMS VIII. Time has been set aside for exercises, questions and discussions.

Participants will be provided with preparatory material in order to better participate in the group exercises.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:
• Apply the basic concepts and principles of signal detection in pharmacovigilance, from simple visualisation and tabulation methods to sophisticated data mining techniques
• Design the signal management process for institutions and companies of various sizes, portfolios and geographical presence, based on the possibilities and limitations of their data and resources
• Understand key messages from the current European and US regulations on signal management, to best manage implications of signals for the future of pharmaceutical companies and products

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

• Signal detection – Theory, methods, data mining
• Signal management – Detection, triage, evaluation, further action
• Signal management – Regulatory expectations
• Signal management process: Strategy for implementation

WHO WILL ATTEND

This course is aimed at professionals who work in:
• Pharmacovigilance (including QPPVs)
• Drug safety and patient safety risk management
• Pharmacoepidemiology
• Information Technology
• Regulatory Affairs
• Pharmacovigilance consultancies
• Quality and Compliance
• Legal

Course level: Intermediate, for professionals with 2-3 years of experience in Pharmacovigilance, or related functions who are working with Pharmacovigilance around signal management.

FACULTY

Calin Lungu
CEO
Drug Development Consulting Services S.A. (DDCS)
Luxembourg

Dr. Lungu has worked for 15 years in drug development, clinical research, pharmacovigilance and quality assurance. Since 2004 he is a EudraVigilance trainer and trained more than 250 EudraVigilance and XEVMPD courses at the EMA, selected European cities and also in the US. He has also trained from 2008 to 2012 the EudraVigilance Data Analysis System course at the EMA and including participants from the EMA and the National Competent Authorities.
DAY 1
08:00  REGISTRATION
08:30  WELCOME AND INTRODUCTION
09:00  SESSION 1

SIGNAL DETECTION – THEORY, METHODS, DATA MINING (1)
Calin Lungu
Signal Detection is a key component of pharmacovigilance science – discovering new effects of medicines in their post-authorisation use. We will present concepts, definitions, data sources, traditional methods of detection, data mining and newest techniques. Participants will exercise the application of best practices in small teams.

10:30  COFFEE BREAK
11:00  SESSION 1 (CONTINUED)

SIGNAL DETECTION – THEORY, METHODS, DATA MINING (2)
12:00  LUNCH
13:00  SESSION 2

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION (1)
Calin Lungu
Signal Management is one of the key pharmacovigilance processes; in this session we will review its position relative to other key processes. The different steps and quality requirements in the process will be explained, with the goal of clarifying the need for IT tools and resources for implementation in various contexts. Participants will work on real life examples in small groups.

14:30  COFFEE BREAK
15:00  SESSION 2 (CONTINUED)

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION (2)
16:30  SESSION 3

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (1)
Calin Lungu
We will review the latest regulatory requirements on implementing and maintaining a signal management process. Again, practical exercises will allow participants to understand how they can develop a policy in signal management, and cope with any inspection on this topic.
18:00  END OF DAY ONE

DAY 2
08:00  SESSION 3 (CONTINUED)

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (2)
09:30  SESSION 4

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (1)
Calin Lungu
This session reviews how regulators, big companies and small companies should design their signal management process, the expected timelines, resources and outcomes from this process, and how the communication of signals should be performed. We will discuss all of these critical issues during this final session, and look at the typical scenarios the industry and regulators face today.

10:00  COFFEE BREAK
10:30  SESSION 4 (CONTINUED)

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (2)
12:00  END OF TRAINING COURSE

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REGISTRATION FORM
Signal Management in Pharmacovigilance
23-24 February 2017, Novotel Bucharest City Centre, Romania

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REGISTRATION FORM
23-24 February 2017, Novotel Bucharest City Centre, Romania

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