Joint DIA/MEB Excellence in Pharmacovigilance
Virtual Live Training Course
Available as Modules 1-5 I From 8 to 26 November 2021

"Excellence in Pharmacovigilance" Module 5: Signal Management

New safety signals may emerge at any time following product launch and must be evaluated for relative risk, medical importance, and likelihood of occurrence. Signal Management is, therefore, one of the crucial "routine" Pharmacovigilance activities. Approaches to Signal Management using qualitative and quantitative methods will be illustrated in a workshop with examples as well as general considerations on signal management in the EEA.

Day 1 25 Nov, 08:30-13:00

08:30 Welcome

09:00 Introduction to Signal Detection in the European Union – Regulatory Perspective

Bianca Mulder, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

11:00 Break

11:30 Signal Management in the European Union – Industry Perspective

Marcela Fialova, Chief Operating Officer and Co-Founder,iVigee, Czech Republic

12:30 Discussion and Q&A

13:00 End of Day 1

Day 2 26 Nov, 09:00-11:45

09:00 Signal Management – Workshop

Bianca Mulder, Pharmacovigilance Assessor, Medicines Evaluation Board, Netherlands

11:00 Discussion and Q&A

11:30 Closing Remarks

11:45 End of Module 5