

DIA/MEB Excellence in Pharmacovigilance Module 4: Signal Management

Virtual Live Training Course

17 November 2022
08:30-15:45 CET



COURSE DIRECTORS

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OVERVIEW

Module 4 covers GVP Modules IX and X.

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.

TARGET AUDIENCE

Professionals with experience in safety related activities of the drug development process and/or those with a need of a holistic overview about all PV related regulatory requirements will benefit most, such as:

- Pharmacovigilance Officers, Managers, Specialists, Experts, or Coordinators
- Regulatory Compliance, Quality or Safety departments Heads, Directors or Managers

Level: /Intermediate

08:30 Introduction to Signal Detection in the EU – Regulatory Perspective

Negar Babae and Evelyn Mulder-Olthof

10:30 COFFEE BREAK

11:00 Signal Management in the EU – Industry Perspective

Jan Petracek

12:00 LUNCH BREAK

13:00 Signal Management – Workshop

Negar Babae and Evelyn Mulder-Olthof

15:00 Discussion and Q&A

15:30 Closing Remarks

15:45 END OF MODULE 4