DIA/MEB Excellence in Pharmacovigilance

Module 1: Post-Marketing

Virtual Live Training Course

14 November 2022
08:30-17:00 CET

COURSE DIRECTORS

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FACULTY

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OVERVIEW

Module 1 corresponds to GVP Modules VI and VII and will cover individual and periodic adverse reaction reporting requirements of marketing authorisation holders in the post-authorisation phase with illustrations based on case studies as practical examples.

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 **Welcome and Introduction**

08:45 **Keynote: PRAC: Present and Future of Pharmacovigilance**
Liana Gross-Martirosyan

09:30 COFFEE BREAK

10:00 **Expedited Reporting Requirements in the Post-Authorisation Phase and Case Studies**
Wendy Huisman

12:30 LUNCH BREAK

13:30 **Preparation of Aggregate Reports (PSUR and DSUR)**
Mark Bailey

15:00 COFFEE BREAK

15:30 **Reporting Requirements in Special Situations in the Post-Authorisation Phase**
Wendy Huisman

16:30 **Discussion and Q&A**

17:00 **END OF MODULE 1**

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