

Introduction to “Excellence in Pharmacovigilance”

This introductory virtual live course includes a concise overview of the objectives and the scope of Pharmacovigilance.

Key definitions based on Community legislation and consensus, such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the CIOMS Working Groups will be explained. Practical examples and exercises will be used to illustrate the basic definitions in Pharmacovigilance and the methods used in Pharmacovigilance.

Level: Beginner.

Day 1 1 Nov, 08:30-12:00

- 08:30 Welcome
- 09:00 History of Pharmacovigilance and basic principles
Wendy Huisman, Director, Vigifit, Netherlands
- 10:00 Break
- 10:30 Legal basis and requirements
Wendy Huisman, Director, Vigifit, Netherlands
- 11:30 Discussion and Q&A
- 12:00 End of Day 1

Day 2 2 Nov, 09:00-12:00

- 09:00 Definitions, tools and methods
Wendy Huisman, Director, Vigifit, Netherlands
- 10:00 Break
- 10:15 Introduction to Risk Communication
Jan Petracek, Director, Institute of Pharmacovigilance, Czech Republic
- 11:30 Discussion and Q&A
- 12:00 End of Course