Introduction to Pharmacovigilance

Delivery: Online, Inhouse **Duration:** 1 days **Cost:** £780 (+ VAT)

Course overview

This course provides a comprehensive overview of the principles of pharmacovigilance (PV), a key function in all pharmaceutical companies to ensure continuous oversight of the benefit/risk of medicines and the early identification and management of safety concerns.

Pharmacovigilance is governed by strict regulatory and legislative standards and guidelines and is subject to regular audits and inspections. Consequences of non-compliance would include, but are not limited to, financial penalties, imposed limitations on/withdrawal of marketing authorisations, and most importantly a potential risk to public health.

Who should attend?

The course is suitable for anyone in the pharmaceutical industry that needs to gain knowledge of pharmacovigilance and drug safety. This could include those working in a pharmacovigilance and drug safety role that are new to pharmacovigilance or those in a junior role wishing to gain more knowledge and understanding.

Also relevant for Trainee QPs and to those working in Quality Assurance, Regulatory or Medical roles who need to understand the basic principles of pharmacovigilance and drug safety and start-up pharmaceutical companies with product/s currently at the clinical trial stage with a need to understand pharmacovigilance/drug safety prior to gaining a MA license.

Course programme

The course covers the following topics:

- What is pharmacovigilance?
- Why is pharmacovigilance important?
- Legislative/regulatory framework
- What is an adverse event/adverse drug reaction?
- Overview – key aspects of pharmacovigilance and operational considerations
- Common inspection findings

Learning outcomes

At the end of the course, you will have gained the following :

- Basic understanding of pharmacovigilance/drug safety (background, definitions) and its importance in promoting patient safety
- Basic knowledge of the legislation/regulations/guidelines governing pharmacovigilance and the consequences of non-compliance
- Understanding of what constitutes an adverse event/adverse drug reaction/safety information
- High-level understanding of key aspects of pharmacovigilance operations and how this contributes to ensuring the timely mitigation of potential risks to patient safety

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