Pharmacovigilance: Drug Safety and Regulations Online Course

£89

Course Overview

Welcome to the Pharmacovigilance: Drug Safety and Regulations course, designed for professionals involved in clinical research, safety monitoring, and regulatory compliance who are seeking to develop or strengthen their understanding of pharmacovigilance principles and practices.

Pharmacovigilance is a critical component of clinical development and post-authorisation activities, focused on the ongoing detection, assessment, and management of safety information. It supports the protection of participants and patients, and contributes to maintaining a positive benefit–risk balance throughout the product lifecycle. This course introduces the purpose and scope of pharmacovigilance, its global regulatory framework, and its integration with broader clinical trial and safety systems.

You will explore key topics including safety data sources, individual case safety reports (ICSRs), aggregate safety evaluation, and risk identification and control. The course also addresses safety communication, regulatory expectations, and the role of pharmacovigilance in supporting informed decision making. By the end of the course, you will have developed a clear understanding of how pharmacovigilance systems operate in practice, and how to apply these principles in a compliant and proportionate way.

Learning Objectives

- Describe the purpose and key components of pharmacovigilance, including its role across the product lifecycle and within the global regulatory framework.
- Identify and differentiate key sources of safety data, including individual case safety reports (ICSRs) and aggregate safety information.
- Explain the principles of risk identification, evaluation, and control, including the use of risk management plans and proportionate risk minimisation strategies.
- Recognise and apply the principles of effective safety communication, including tailoring information to different audiences and meeting regulatory expectations.

Pharmacovigilance: Drug Safety and Regulations Online Course

£89

Course Contents:

- Introduction to Pharmacovigilance
- Global Regulatory Landscape
- Pharmacovigilance Systems
- Safety Data Sources
- Safety Surveillance and Individual Case Safety Reports (ICSRs)
- Aggregate and Periodic Safety Evaluation
- Signal Identification, Evaluation, and Risk Assessment
- Risk Identification and Risk Control
- Post-Authorisation Safety Studies (PASS)
- Safety Communication
- Inspections, Audits, and Demonstrating Quality
- Scenarios
- Exam

Duration:

Approx. 2 hours.
As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.

www.integrityclinicalcompliance.com