

KEY



Face-to-Face Training



Online Course



Blended Learning

Core Track (17 Credits Required)

Basic Safety Concepts: Pharmacoepidemiology, Pharmacogenomics, Toxicology Studies, and Clinical Pharmacology (1 Credit)

Drug Safety Across the Product Lifecycle (4 Credits)

OR

Introduction to Drug Safety (1 Credit)

Drug Safety Regulatory Requirements (1 Credit)

Pre-marketing Clinical Trial Safety (1 Credit)

Post-marketing Safety Management (1 Credit)

Basics of Signal Detection and Pharmacoepidemiology (1 Credit)

Safety Audits and Inspections (1 Credit)

Product Labeling (1 Credit)

Benefit-Risk Assessment and Management (2 Credits)

Safety Risk Management: A Focus on US REMS and EU RMPs (2 Credits)

The Pharmacovigilance Quality Management System (2 Credits)

Safety Risk Communication for Medical Products (2 Credits)

Techniques for Writing Clear, Concise Safety Reports (1 Credit)

Elective Track (2 Credits Required)

QPPV Toolbox (2 Credits)

Clinical Pharmacology Approach in the Identification and Management of Adverse Drug Reactions (2 Credits)

Advanced Signal Management-Detection, Evaluation, and Decision-Making (2 Credits)

Selecting and Managing Outsourced Safety Providers (2 Credits)

Exam

