







**Online Course** 



**On-Demand Course** 

## **Core Track (17 Credits Required)**

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

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 Across the Lifecycle (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)

Essentials of Safety Medical Writing (1 Credit)

## **Elective Track (2 Credits Required)**

Medical Writing of Periodic Safety Update Reports (PSUR/PBRER) (2 Credits)

QPPV Toolbox (2 Credits) Clinical Pharmacology Approach of Idenitification and Management of Adverse Drug Reactions (2 Credits)

Risk Management Plan Creation: Best Practice in Medical Writing (2 Credits) Selecting and Managing Outsourced Safety Providers (2 Credits)

## Exam



Safety and Pharmacovigilance Certificate Program Digital Credential