Pharmacovigilance Auditing

By the end of each module you'll be able to accomplish the following objectives:

Module 1: Overview and PV Legislation

- Explain why pharmacovigilance is needed
- Provide an overview of the U.S. Food and Drug Administration's (FDA) regulatory pharmacovigilance system
- Provide an overview of the European Union's (EU) regulatory pharmacovigilance system
- Describe the execution of critical pharmacovigilance systems
- Audit pharmacovigilance systems against regulatory requirements with a risk-based approach

Module 2: Definitions and General Processes

- List sources of safety information
- Define key terms in ICH E2A
- Explain how pharmacovigilance is applied in clinical trials
- Explain how pharmacovigilance is applied post-marketing of a drug
- Describe the role of the Qualified Person for Pharmacovigilance in the EU

Module 3: PV Databases and Reporting

- List the steps necessary to document a safety report
- List pharmacovigilance database requirements
- Code Adverse Events in the PV database
- Determine if an Adverse Event is "serious"
- Describe the three distinct reporting requirements for ICSRs
- Describe aggregate reporting requirements in the EU and U.S.

Module 4: PV Auditing

- Describe the U.S. Food and Drug Administration's (FDA's) pharmacovigilance (PV) regulatory inspection process
- Describe the purpose and types of PV audits
- Prepare for a PV audit
- Establish the scope of a PV audit
- Conduct a PV audit