



Safety professionals in today's rapidly changing global regulatory environment must have a strong foundation in safety surveillance and pharmacovigilance, which requires ongoing, comprehensive, and up-to-date training and education.

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COURSE 2: CLINICAL SAFETY SURVEILLANCE

With interactive, real-world case studies, Course 2 covers the collection, assessment, and reporting of adverse events (AEs) during the clinical development phase of a drug or biologic. It includes US and EU regulations and related ICH guidance documents pertaining to clinical safety surveillance of an investigational medicinal product and provides a step-by-step overview of the responsibilities and activities of the study sponsor, from receipt of serious adverse event (SAE) reports from investigators, through all stages of case processing including causality assessment and reporting to regulatory authorities.



Length: 4 hours

Audience: Individuals interested in entering the field of drug safety and pharmacovigilance; professionals already in the biopharmaceutical industry practicing in the areas of clinical research, drug safety, regulatory affairs, and GCP compliance.

LEARNING OBJECTIVES:

- Describe the purpose of safety surveillance in clinical trials
- Explain the general regulatory oversight of clinical trials in the US and EU
- List the key stakeholders in a clinical trial and explain their role in assuring the safety of study subjects
- Differentiate between US and EU regulations and guidances, and explain the influence of ICH and CIOMS
- Define key terms and concepts central to clinical safety surveillance (e.g., serious, expected, relatedness, dechallenge, rechallenge)
- Describe the purpose and content of Investigator's brochure and the expected AE list
- List the responsibilities of the clinical trial investigator in AE reporting
- Understand the data fields collected for AEs and SAEs on reporting forms
- Identify the key steps in the workflow for processing an SAE report
- Describe in what situations a 7- and/or 15-day expedited safety report is required
- Determine how to triage SAE reports, and determine if an SAE report meets expedited regulatory reporting requirements
- Learn the important components of an SAE case narrative
- Demonstrate how and when to write a query to request followup information
- Describe when it is appropriate to unblind treatment assignment for SAE reports
- Understand the difference between the clinical and safety databases, and the purpose of database reconciliation
- Explain what is required for submitting reports to US and EU regulatory authorities and investigators
- Explain how overdose and pregnancy are typically reported in clinical trials