

Drug Development Process

- Describe the role of the drug safety function in the medical product lifecycle and in the company
- Articulate the basic principles of clinical pharmacology
- Explain the clinical, regulatory, and commercial requirements for early- through late-stage drug development
- Discuss the role of key drug safety professionals within the drug safety function
- Summarize the basics of toxicology studies and the limitations in predicting human toxicity

Scientific Concepts of Pharmacovigilance

- Outline the process for assessing drug adverse events
- Describe the fundamental concepts of pre-market safety and pharmacovigilance and their application
- Describe the fundamental concepts of post-marketing drug safety and pharmacovigilance and their application to post-marketing safety surveillance
- Explain the techniques for writing clear, concise safety reports including ICSRs, safety summaries, and periodic reports
- Summarize the investigation process for examining and substantiating individual case reports and aggregate data
- Identify the data sources, data capture, data management practices, and statistical methods for preparation and analysis of clinical and post-marketing safety data
- Outline approaches to signal detection and data mining as part of pharmacovigilance operations
- Describe how to implement effective signal assessment and management tools and techniques
- Summarize principles of pharmacoepidemiology, pharmacogenomics, and other drug safety sciences to analyze potential safety issues and better understand the patient population
- Articulate concepts of pre-marketing risk assessment and their role in drug development
- Explain the application of benefit-risk analysis methodologies in pharmacovigilance
- Describe risk mitigation and minimization strategies and the principles and processes for developing effective and compliant risk management plans (RMPs)
- Describe risk mitigation and minimization strategies and the principles and processes for developing effective and compliant Risk Evaluation and Mitigation Strategy (REMS)
- Discuss how to assess REMS and RMP effectiveness
- Distinguish different communication methods to improve the use of medicines, to maximize patient benefit, and minimize risk

Quality Management

- Describe the development and maintenance of pharmacovigilance standard operating procedures (SOPs)
- Explain the development and maintenance of pharmacovigilance-related documents including Pharmacovigilance System Master File, Safety Management Plans, and Safety Data Exchange Agreements across clinical study programs and post-marketing
- Summarize how to design, develop, and manage a Quality Management System
- Discuss how to assess the effectiveness of the Quality Management System
- Describe how to effectively prepare for and conduct audits and inspections
- Outline how to develop the corrective action plan and assess its effectiveness

Regulatory Requirements

- List the relevant US and EU rules, regulations, and initiatives governing both safety reporting and processing for clinical trial and post-marketing environments, including CIOMS and ICH guidelines
- Interprets and apply US and EU drug safety regulations
- Describe the regulatory requirements and components of US Risk Evaluation and Mitigation Strategies (REMS) and the EU Risk Management Plan (EU-RMP)
- Explain the requirements and procedures for complying with post-marketing obligations
- Define the types of inspections and audits, how they differ in the US and EU, and how to prepare for a health authority inspection
- Describe the regulatory reporting requirements for pharmacovigilance-related documents including individual case safety reports (ICSRs), NDA and IND annual report summary statements, and periodic aggregate reports (PSUR/PBRER, PADER, DSUR, IND annual reports, etc.)
- Describe product labeling documents and the pharmacovigilance role in their development and negotiation
- State the role of pharmacovigilance in generating responses to regulatory health authority safety inquiries