MEDCLINIGEN

PHARMACOVIGILANCE

Advanced Course Syllabus • Drug Safety & Pharmacovigilance

ADVANCED PHARMACOVIGILANCE SYLLABUS

12 structured modules covering drug-safety fundamentals, PV workflows, ICSR processing, causality, global reporting systems, aggregate reports, signal detection, career development and interview preparation.

Module 1 | Introduction & History of Pharmacovigilance

- Introduction to Pharmacovigilance
- History & Evolution of PV
- Important Historical Drug Safety Events
- Need & Importance of Pharmacovigilance
- Role of PV in Drug Safety

Module 2 | Basic Concepts & Terminologies

- Pharmacovigilance Terminology
- Adverse Event (AE)
- Adverse Drug Reaction (ADR)
- Serious Adverse Event (SAE)
- Types of ADRs
- Expected & Unexpected Reactions
- Medication Errors
- Special Situations in PV
- Drug Safety Concepts

Module 3 | Regulatory Guidelines in Pharmacovigilance

- WHO Guidelines
- ICH Guidelines
- CIOMS Guidelines
- ICH Q, S, E & M Guidelines
- ICH Pharmacovigilance Guidelines
- Regulatory Framework for Drug Safety

Module 4 | Pharmacovigilance Process

- Overview of PV Workflow
- Safety Data Collection
- Case Identification
- Case Processing
- Medical Review
- Data Entry & Quality Review
- Follow-up
- Safety Reporting

Module 5 | Challenging Concepts in Pharmacovigilance

- Special/Complex Cases
- Duplicate Cases
- Follow-up Cases
- Literature Cases
- Medication Errors
- Overdose
- Off-label Use
- Misuse & Abuse
- Pregnancy & Lactation Cases
- Product Quality Complaints
- Special Situations

Module 6 | Causality Assessment

- Concept of Causality
- Causal Relationship Assessment
- WHO-UMC Causality Assessment
- Naranjo Algorithm
- Temporal Relationship
- Dechallenge & Rechallenge
- Alternative Causes
- Assessment of Drug–Event Relationship

Module 7 | Individual Case Safety Reports (ICSR)

- ICSR Fundamentals
- Sources of Safety Information
- Case Intake
- Case Triage
- Case Validity
- Data Entry
- Case Processing Workflow
- Medical Review
- Quality Control
- Follow-up
- Case Closure
- ICSR Processing Tools

Module 8 | ADR Reporting Systems — Global

- ADR Reporting Systems
- Spontaneous Reporting Systems
- Regulatory Reporting
- National PV Systems
- Reporting Systems of Different Countries
- Global Drug Safety Databases
- Safety Reporting Requirements

Module 9 | Aggregate Safety Reports

- Concept of Aggregate Reports
- Periodic Safety Reports
- PSUR/PBRER
- DSUR
- Safety Data Analysis
- Benefit–Risk Evaluation
- Signal/Trend Evaluation
- Regulatory Submission of Aggregate Reports

Module 10 | Signal Detection & Drug Safety

- Signal Detection Concepts
- Identification of Safety Signals
- Signal Evaluation
- Signal Validation
- Signal Assessment
- Risk Identification
- Benefit–Risk Assessment
- Risk Management

Module 11 | Career Opportunities in Pharmacovigilance

- Pharmacovigilance Career Path
- Drug Safety Roles
- ICSR Processing Roles
- Medical Reviewer
- Safety Associate
- Signal Detection Roles
- Aggregate Reporting Roles
- PV Career Opportunities
- Skills Required for PV Professionals

Module 12 | Pharmacovigilance Interview Preparation

- Important PV Interview Questions
- ICSR-Based Questions
- ADR/SAE-Based Questions
- Causality Assessment Questions
- Regulatory & Guideline Questions
- Case-Processing Scenarios
- Practical & Scenario-Based Questions