








ONLINE

Certificate Course in Pharmacovigilance

Comprehensive Program for Healthcare Professionals.

QUICK SUMMARY

-  Commencement - February 2025
-  11 Live Sessions
-  3 Quizzes + 2 Case Assessments
-  16 Hours
-  Course Completion Certificate

[TAKE THE COURSE >](#)

Course Description

This Pharmacovigilance Certificate Course is an immersive, comprehensive program designed to prepare participants for a pivotal role in the healthcare and pharmaceutical industries, emphasizing patient safety and drug efficacy. This course provides an in-depth exploration of pharmacovigilance fundamentals, advanced methodologies, and regulatory frameworks essential for monitoring and managing the risks associated with pharmaceutical products. Participants will journey through every stage of the pharmacovigilance lifecycle, from adverse event detection and assessment to regulatory compliance and safety signal management.

Key Learning Objectives

By the end of this course, participants will be able to:

- Gain a comprehensive understanding of pharmacovigilance principles and the importance of drug safety in healthcare.
- Recognize and classify adverse drug reactions, using global reporting systems to ensure effective documentation.
- Understand regulatory compliance and guidelines essential for pharmacovigilance, including FDA, EMA, and WHO standards.
- Develop skills in data collection, analysis, and signal detection for identifying and managing drug risks.
- Learn to communicate drug safety information effectively, including crisis management for recalls or alerts.
- Apply pharmacovigilance practices to special populations, such as pediatrics and geriatrics.
- Explore career paths in pharmacovigilance, gaining practical skills and knowledge for industry success.

CURRICULUM

- **Module 1: Introduction to Pharmacovigilance** **Feb 03**
Covers the basics of pharmacovigilance (PV), its history, and its significance in healthcare. Introduces key terms, objectives, and the role of PV in ensuring medication safety.
- **Module 2: Classification and Scales in Pharmacovigilance** **Feb 05**
Examines the classification of adverse drug reactions and causality assessment scales, such as Naranjo and WHO-UMC, to assess causality, severity, and preventability of drug-related events.
- **Module 3: MedDRA: Medical Dictionary for Regulatory Activities** **Feb 07**
Provides an overview of MedDRA terminology, structure, and applications in PV, including standardized coding of medical information, classification levels, and its importance in regulatory reporting.
- **Module 4: Surveillance Techniques in Pharmacovigilance** **Feb 10**
Explores active and passive surveillance techniques, spontaneous reporting, cohort event monitoring, and post-marketing surveillance to monitor drug safety in real-world settings.
- **Module 5: Signal Detection and Assessment** **Feb 12**
Covers methods for detecting safety signals from PV data, including disproportionality analysis and data mining, and explains the signal evaluation process and decision-making criteria.
- **Module 6: Regulatory Pharmacovigilance** **Feb 14**
Discusses global and regional PV regulations, including ICH, FDA, EMA, and CDSCO guidelines, covering reporting requirements, regulatory compliance, and the PV lifecycle from drug development to post-market.
- **Module 7: Quality Assurance and Compliance** **Feb 17**
Introduces quality assurance measures in PV, such as auditing, SOPs, and GVP (Good Pharmacovigilance Practices), emphasizing maintaining PV data quality, consistency, and compliance with regulatory standards.
- **Module 8: Pharmacovigilance in the Pharmaceutical Industry** **Feb 19**
Focuses on how PV is integrated within pharmaceutical companies, covering in-house PV processes, industry roles, risk management plans, and challenges in ensuring drug safety from development through marketing.
- **Module 9: Pharmacovigilance Databases: An Overview** **Feb 21**
Introduces major PV databases, such as WHO VigiBase, etc focusing on their roles in adverse event reporting, data entry standards, and analysis tools.
- **Module 10: Panel Discussion** **Feb 24**
Discussion about case assessments, career opportunities, and anything you're looking for direct guidance.

FEATURES

- ✓ Expert Led Modules
- ✓ Flexible Online Learning
- ✓ Certificate of Completion
- ✓ Access to lectures
- ✓ Interactive Quizzes
- ✓ Case Assessments
- ✓ Career Guidance Session
- ✓ Concession for Group Enrollments



It's not just about building a **career**; it's also about understanding and exploring interdisciplinary systems and processes.

FEE STRUCTURE



1299 INR/Scholar

Preferable

- 11 Live Sessions
- Access to recordings
- 3 Quizzes + 2 Case Assessments
- Career Guidance Session
- Certificate of Program Completion



999 INR/Scholar/Group of Min 5 Scholars

Best Choice

- 11 Live Sessions
- Access to recordings
- 3 Quizzes + 2 Case Assessments
- Certificate of Program Completion (Hard Copy)
- Career Guidance Session
- Placement Assistance +

Guardians of Medicine, Champions of Safety — Pharmacovigilance in Action!