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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

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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 postmarketing 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.

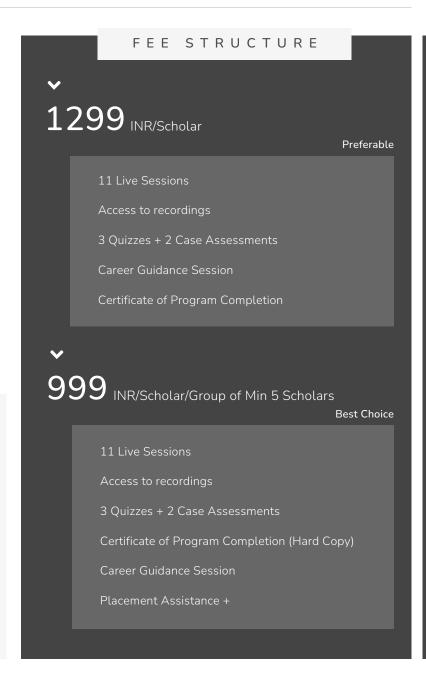


FEATURES

- Expert Led Modules
- Flexible Online Learning
- Certificate of Completion
- Access to lectures
- Interative 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.





Department of Vigilance

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Advancing **Pharmacy** Education,

In Every Possible Way!