



Pharmacovigilance:-

Class Room: Training Fee & Duration : 20K & 2 Months	Online Training Fee & Duration : 23K & 2 Months
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Module I Pharmacovigilance

- Introduction
- Historical Overview
- Basic principles of Pharmacovigilance in Clinical Trials
- Methodologies for Pharmacovigilance

Module II Regulations in Pharmacovigilance in Clinical Research

- FDA and EU perspectives
- Drug Regulatory Activities MedDRA
- Regulatory Aspects in Pharmacovigilance
- EudraVigilance
- Regulations in Pharmacovigilance in Clinical Research

Module III Adverse Drug Reactions and Safety Reports

- ADR Reporting
- Causality Assessment of Suspected Adverse Drugs Reactions
- Periodic Safety Update Reports (PSURs) For Marketed Drugs (ICH E2C)
- Expedited Reporting Requirements
- Individual case safety reports
- Periodic safety update reports
- Electronic safety reporting
- WHO & safety monitoring

Module IV Signal Analysis

- Definition of signal and type of signal
- Conducting signal detection in clinical and post marketing surveillance
- Defining signal in relation to risk/benefit
- Signal generation to decision making
- Signal Detection Tools
- Understanding signals & benefit risk determinations

Module V Compliance to Clinical Safety and Pharmacovigilance Regulations

- Review of benefit-risk assessments and management
- Scope of Pharmacovigilance inspection and conduct of inspection

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- Internal audit of pharmacovigilance activities of a company
- Pharmacovigilance inspection reports
- Pharmacovigilance compliance and inspection
- Quality System in Pharmacovigilance : Good Practices, SOPs, Preparation for Audits & Inspections
- Scope of Pharmacovigilance inspection and conduct of inspection
- Internal audit of pharmacovigilance activities of a company
- Key Functionalities of the Adverse Event Systems
- Quality System in Pharmacovigilance : Good Practices, SOPs, Preparation for Audits & Inspections

Module VI Pharmacovigilance Management and Importance

- Pharmacovigilance Database
- Setting up a Pharmacovigilance Centre in Industry
- Management of Pharmacovigilance Data
- Risk Management in Pharmacovigilance
- Data management & software solutions
- Effective communication in pharmacovigilance
- Pharmacovigilance in special situations
- Pharmacovigilance capacity building

HR-Interview Etiquettes:-

- Communication Skill
- Office etiquettes
- E-mail etiquettes
- Presentation skills and Public speaking
- Interview preparation
- CV preparation
- Mock interviews
- Assessments