PHARMA ANALYTICA

Pharmacovigilance Curriculam

Course : Online /Offline

Duration : 2 months

Course contents/Topics

MODULE - I

- ✓ History of pharmacovigilance
- ✓ Fundamentals of pharmacovigilance
- ✓ Economic Impact of ADR
- ✓ Overview of regulatory bodies of pharmacovigilance.
  - ICH and CIOMS Guidelines
  - WHO pharmacovigilance program
  - CDSCO and Pharmacovigilance program of India
  - European union and European Medical agency
  - United states food and drug administration (USFDA)
- ✓ Region specific Pharmacovigilance requirements.
  - ADR reporting timelines
  - PSUR submission timelines
  - Types of reports
- ✓ Segments of safety data generation
  - Pre-clinical Phase
  - Clinical phase
  - Post approval Phase

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MODULE - II

- ✓ Terminologies employed in pharmacovigilance
  - Adverse event and Adverse drug reaction.
  - Types of ADR
  - Expectedness /Unexpectedness
  - Minimum criteria for reporting
  - Reference safety information
- ✓ Clinical Trails
  - Overview of Clinical Trails
  - Basic definitions
  - Sponsor responsibilities
  - Reporting of adverse events in clinical trial phase
- ✓ Reference Safety Information(RSI)
  - Overview of RSI Documents
  - Types of RSI Documents
  - Region specific Requirements
  - Contents of RSI documents
  - Paths of RSI Documents
- ✓ Individual Case safety Reporting
  - Importance of safety monitoring/ Reporting
  - Sources of reports
  - Types of reports
  - Case processing
  - Data entry into safety database
  - Narratives
  - Methods of causality Assessment
  - Pharmacovigilance safety databases
- ✓ Aggregate reporting
  - Overview of aggregate reports
  - Types of aggregate reports
  - Region specific regulatory requirements
  - General principles of aggregate reports
  - Overview of Line listing generation from safety databases
  - Contents and Various types of aggregate reports

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MODULE - III

- ✓ Overview of Development safety Update reports
  - Region specific regulatory requirements
  - General Principles of DSUR
  - Contents of DSUR.
- ✓ Overview of risk management Plans
  - Region specific regulatory Requirements
  - General Principles of RMPs
  - Contents of RMPs
- ✓ Medical Dictionary for Regulatory Activities
  - Objectives of MedDRA Development
  - Scope of MedDRA
  - MedDRA and MSSO
  - WHO and MedDRA
  - Standardized MedDRA Queries(SMQs) and System Organ Class(SOC)

MODULE - IV

- ✓ Overview and Methods of Signal Detection
- ✓ Anatomical, Therapeutic and chemical Classification of Drugs
- ✓ Defined Daily doses
- ✓ Pharmacogenomics
- ✓ Pharmacovigilance Industries and Services.
- ✓ PV- QA Roles

MODULE - V

- ✓ Discussion on Queries
- ✓ Interview Preparation
- ✓ Personal Interview.