

Pharmacovigilance/ Drug Safety theory:

- History and overview of Pharmacovigilance
- Regulatory Authorities country wise
- Pharmacovigilance in India
- Spontaneous reporting
- Active pharmacovigilance
- Cohort Event Monitoring
- Adverse Events and its types
- Drug Safety in clinical trials and post marketed drugs
- Different sources of Adverse Events reporting
- Different types of AE Reporting Forms
- Expedited reporting and its timelines
- Aggregate reporting
- Different departments working on Pharmacovigilance
- Business workflow of Pharmacovigilance
- Minimum criteria for the case
- Causality assessment of the adverse event
- Expectedness assessment of the adverse event
- Seriousness assessment of the adverse event
- MedDRA and WHODD coding
- SAE narrative writing and Templates
- PBRER/PSUR and its submission timelines
- E2A-E2F Guidelines
- PADAR
- Explanation of Safety Signals, Signal Detection at UMC
- Signal publication and communicating signal
- Risk management

Practical Hands-on Training on Oracle Argus Safety Database :

Argus Console

- PV Business process
- Introduction to Oracle Argus Safety Database

- Family, Product and License creation
- Clinical Study configuration
- Access management : Sites, users and Groups creation
- Workflow Configuration
- Case priority Configuration
- Case Numbering
- LAM case Numbering
- Field Validation
- Code list Configuration
- Field label Configuration
- Auto narrative Configuration

Argus Safety Module

- Different icons used during the case processing and their purpose.
- Different tabs used in case processing
- Case Bookin and Data entry
- Case Processing of ICSR
- Case Triage
- Performing Validation
- Case Routing Based on workflow
- Case Quality check, Medical review
- Duplicate case check or verification
- Report Generation for Regulatory Submission
- Expedited Reports and Aggregate Reports
- Creating PSURs, CTPRs, NDA and IND reports
- Creating Case data analysis reports
- Unblinding the clinical trial cases
- Locking and unloking Case
- Follow Up for Case
- Query generation : Action Items
- Resolving queries using contact Logs
- Case Bookin in LAM and Routing to Central Safety database
- MedDRA coding and WHO DD coding
- Narrative Writing