Course Curriculum:

- Clinical Development process
- Different phases of Clinical Trials
- SOPs, Protocol, Investigator's Brochure
- Informed Consent process
- SAE reconciliation
- IRB/IEC
- ICH-GCP Guidelines
- History and overview of Pharmacovigilance
- Introduction and responsibilities of USFDA, EMA and CDSCO
- Pharmacovigilance Scenario
- Adverse Events and its types
- Passive pharmacovigilance-Spontaneous reporting
- Active Pharmacovigilance-Cohort Event Monitoring
- Drug Safety in clinical trials and Post Marketing Surveillance
- Different sources of Adverse Events reporting
- Different types of AE Reporting Forms
- Expedited Reporting and its timelines
- Different departments working on Pharmacovigilance
- Roles and responsibilities of case receipt unit
- Roles and responsibilities of Triage unit
- Four factors for the reportable case
- Seriousness criteria of adverse event
- Expectedness or Listedness of adverse event
- Causality assessment of the adverse event
- Importance and procedure of duplicate check
- Data Entry
- Case bookin or initiation
- Case processing
- MedDRA and WHODD coding
- SAE narrative writing
- Case quality check, Medical review and its submission
- PSUR and its submission timelines

Practical Hands-on Training on Oracle Argus Safety Database Argus Console

- PV Overview
- PV Business process
- Introduction to Oracle Argus Safety Database
- Family, Product and License creation
- Study creation
- Sites, users and Groups creation
- Workflow Configuration
- Expedited Report Configuration
- Case priority Configuration
- Case Numbering

- Field Validation
- Code list Configuration
- LAM (Local Affiliate Module) Configuration

Argus Safety

- Different icons used during the case processing and their purpose.
- Different tabs used in case processing
- Case Routing Based on workflow
- Minimum requirements for a case bookin
- Duplicate case check or verification
- Case Bookin and Data entry
- Case Processing
- Case Quality check
- Medical review of Individual Case Safety Reports (ICSRs)
- Narrative Writing
- Case Bookin in LAM and Routing to Central Safety database
- MedDRA and WHO DD coding
- Different Case Studies
- Report Generation for Regulatory Submission
- Expedited Reports and Aggregate Reports
- Periodic Reports: PSURs, CTPRs, IND and NDA

You will be extensively involved in:

- Data entry of Individual Case Safety Reports (ICSRs) into the Argus Safety database
- Processing of all incoming cases in order to meet timelines
- Writing a detailed medically oriented description of the events in the form of safety narrative writing
- Perform the duplicate search in Argus safety database
- Assessment of seriousness, expectedness/listedness of Adverse Events
- Evaluate the entered cases as per quality review checklist in terms of quality, accuracy, and completeness against the source documents provided
- Performing QC review of the cases to meet case processing timelines
- Coding of adverse events with the help of MedDRA and labeling the events
- Coding of suspect and concomitant drugs using company and WHO-DRUG dictionaries.
- Meeting the timelines and supporting global regulatory submissions in expedited reporting of ICSRs
- Preparation of PSURs for regulatory submissions
- Entry of Adverse events in Local Affiliate Module (LAM) and Routing Local events to central Argus safety
- Codelist Configuration in Argus console
- Creating Sites, Users, User groups
- Creating Products, Licenses, Studies and Expedited Reporting Rules
- Configuring Workflow States and rules
- Knowledge of Advanced conditions; Setting up of field validation to ensure consistency of data