ASPIRE TECHSOFT

ISO 9001: 2015 Certified Training Institute

Clinical Data Management

Introduction to Clinical Research

- Terminologies in Clinical Research
- Advantages of CR in India
- Introduction to Clinical Research - Notes
- Introduction to Clinical Research Quiz

Drug Development Process

- Overview of Drug Development
- Clinical trial phases
- BA/BE Studies
- Drug Development Notes
- Drug Development Quiz

Clinical Practice (GCP) - ICH E6

- History Development of International Regulations in Clinical Research
- Good Clinical Practices
- Ethics committee
- Investigator Responsibilities
- Sponsor Responsibilities
- Protocol and Investigator Brochure
- Essential Documents

Clinical Data Management

- CFR Part 11
- CRF_Design_2
- Introduction to CDM
- Data Entry Methods
- Query Management
- Source data validation
- Future of Data Management

Pharmacovigilance

- Adverse Event Reporting
- Recording of Event
- Medical Management of Adverse Events
- Handling DeathH
- Clinical Safety and Pharmacovigilance
- E2A - Clinical Safety and Data Management
- Media 436
- Naranjo Assessment
- Order and Formulate to Determine the Quantum

Regulatory Affairs

- Application of Permission
- Approval of Clinical Trial
- CDSCO
- Code of Federal Regulation (CFR)
- CT_Rules_2019
- ICMR Guidelines
- Medical Devices
- ICMR Guidelines
- DoH Oct 2013
- Guidelines for Industry