Job Offers

- Clinical Research Coordinator
- Clinical Research Associate
- Clinical Research Physician
- Clinical Trail Manager
- Clinical Investigator
- Clinical Data Coordinator
- Clinical Data Associate
- Clinical Data Coordinator
- Clinical Data Analyst
- Clinical Data Base Developer
- Clinical Data Base Manager
- Drug Safety Associate
- Drug Safety Physician
- Pharmacovigilance Scientist
- Associate Operation Specialist
- Medical Writer
- Regulatory Affairs Specialist
- Medical Coding
- Clinical SAS Programmer
- Bio Statician
- Clinical Standard Architect
- SDTM Programmer

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Clinical Research

- Module1:Drug Discovery and Development
- Module2:Preclinical Studies
- Module3:Basics of Clinical Trials & Clinical Research
- Module4:Terminology & Definitions in Clinical Trials
- Module5:Types and Phases of Clinical Trials
- Module6:Good Clinical Practices (GCP)
- Module7:BA/BE Studies
- Module8:Research Methodology & Clinical Trial Design
- Module9:Clinical Trial Regulatory Affairs
- Module10:Bioethics
- Module11:Preparations & Planning for Clinical Trails
- Module12:Essential Documentation in Clinical Trails & Regulatory Submissions
- Module13:Clinical Trail Operations and Monitoring
- Module14:Responsibilities of Clinical Research Professionals
- Module15:21 CFR 11
- Module17:Informed Consent Document
- Module19:Protocol Development
- Module20:Intellectual Property Rights (IPR) and Patent Laws
- Module21:SOP Development for Clinical Trail Operations.

Pharmacovigilance

- Module1:History and over view of Pharmacovigilance
- Module2:Introduction and responsibilities: USFDA, EMA and CDSCO
- Module3:Pharmacovigilance in India
- Module4:Clinical Development process
- Module8:Different sources of Adverse events reporting
- Module9:Different types of AE reporting Forms
- Module10:Expedited reporting and its timelines
- Module11:Different departments working on Pharmacovigilance
- Module12:Roles and responsibilities of case receipt unit
- Module13:Roles and responsibilities of Triage unit
- Module15:Seriousness criteria of adverse event
- Module16:Expectedness or Listedness of adverse event
- Module17:Causality assessment of the adverse event
- Module18:Introduction to safety databases and different types
- Module19:Importance and procedure of duplicate check
- Module20:Practical Training will be provided on Case Processing, Narrative Writing, MedDRA & WHO Drug Coding.
- Module21:SAE Reconciliation -Reviewed SOP for Reconciliation of the serious adverse event database
- Module22:PSUR and its submission timelines.
- Module23:Oracle Argus Safety Database (Comprehensive Theory and Practical)
- Module24:MedDRA Dictionary (Comprehensive Theory and Practical)
- Module5:Different phases of clinical Trials
- Module6:Adverse events and its types
- Module7:Drug Safety in clinical trials and post marketed drugs

Clinical Data Management

- Module1:Introduction of Clinical Data Management Process
- Module2:Data Management Plan
- Module3:EDC (Electronic Data Capture)
- Module4:CRF Design (Paper)
- Module5:e-CRF Development
- Module6:Data Validation and Specification (DVS) Development
- Module7:CDM QC Testing
- Module8:CDM UAT Testing
- Module9:Data Processing
- Module10:Report Generation and Data Transfer
- Module11:Data Cleaning
- Module12:Study Freezing and Locking
- Module13:Oracle Clinical (Comprehensive Theory and Practical)
- Module14:Inform Architect (Comprehensive Theory and Practical)
- Module15:Oracle Central Designer (Comprehensive Theory and Practical)
- Module16:Oracle Inform GTM (Comprehensive Theory and Practical)

Drug Regulatory Affairs

Module 1 : Introduction to Global Regulatory Authorities for pharma and healthcare industries
Module 2 : Drug Development Process, Clinical Trials and related norms and regulations
Module 3: GMP and other good practices
Module 4: Documentation of drug trials and regulatory filings in US, Europe, UK, India,Japan, Canada, Australia, South Africa, etc.
Module 5: Quality Assurance and Drug Regulations, ICH and WHO guidelines
Module 6: Dossier preparation in CTD format, eCTD submissions
Module7: Healthcare Industry IPR, Patents, copyrights and Trademarks
Module 8: Pharma and Healthcare products- Marketing, Import and Export regulations
Module 9: Compliance guidelines, Govt. Audits (FDA, MHRA, PMDA, TGA, DCG, etc)and Breach reports
Module 10: Indian GMP Regulations
Module 11: Industry specific case studies Mini Project.
Preparation of Drug Applications (Dossiers) in Different formats
a) CTD
b) ACTD

Medical Writing

Module 1: Introduction to Medical and Clinical Research Writing.
Module 2 :Opportunities in Medical Writing
Module 3: How to get yourself published?
Module 4:Followed by 1 set of practical writing assignment
Module 5:Overview of online and offline writing environment
Module 6: Effective Web Content Writing Techniques
Module 7: Followed by 1 set of practical writing assignment
Module 8: Introduction to basic and advance research techniques
Module 9: Sources for research based writing
Module10 :Scientific Writing
Module11: General rules for scientific writing
Module12: Clinical trials reports, overview and summary documents,
Module 13 Narrative documents, tabular summary

SAS

Base SAS:
Module1:Introduction to SAS
Module 2: Components o SAS Program and Code Writing
Module 3: Running SAS Programs
Module 4:Mastering Fundamental Concepts
Module 5: SAS Options 8. Types of Input Statements
Module 6: SAS Format and Informats
Module 7: Using Advanced Input Techniques
Module 8:Combining and Sorting Datasets
Module 9: Merging and Updating Data
Module 10. Performing Conditional Processing
Module 11: Creating Customized List Reports
Module 12: Arrays 18. Creating Enhancing List and Summary Reports
Module 13: Creating Proc Tabulate
Advance SAS:

SAS Macros

1. Fundamentals of Macros
2. Macro Application
3. Macros Program Structure
4. Macros Statements
5. Macro Variables
6. Macro Functions

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