cliniminds™
Academy for Clinical Research Training & Management
An ISO 9001:2000 Certified Academy

An ISO 9001:2008 Certified Academy

ICH GCP Certificate Program in Clinical Research for Medical Practitioners

This is a comprehensive educational program, designed for the Medical Practitioners aspiring to work in the field of clinical research or allied professions like Investigator Site, Ethics Committee & Pharmacovigilance. The program provides complete overview and practical environment in the field of clinical research. The program would candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Program would help Medical Practitioners in developing career in the field of clinical research.

Mode : Online/Distance Learning

Duration : 6 Months

Eligibility : MD, MS, MBBS, BDS, Other Medical Practitioners.

Methodology : Printed Training Modules; Online E learning System

Internship : An online internship program would be arranged with the CRO, Pharmacovogililance, pharmaceutical or QA firm. Certificate would be awarded Upon Successful completion of the internship.

Examination : Online MCQs

Certificate : Certificate would be awarded upon successful completion of the program.

Accreditation : Program is Certified & Accredited by the **Swiss Association of Pharmaceutical Professionals** (SwAPP) & **Swiss Society of Pharmaceutical Medicines.**

Job Assistance : Limited placement assistance would be provided. CVs of successful candidates would be sent to the potential employers.

Fee payment : Fee can be paid by Credit / Debit card through Paypal. We also accept bank wire transfer.

Program Details : The program would cover

- Introduction to Clinical Research & Phases in Clinical Research
- Principles of Good Clinical Practices - ICH GCP
- Ethical Considerations in Clinical Trials

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- Indian GCP Guidelines, Schedule Y & ICMR Guidelines
- Regulations in Clinical Research
- Sponsor/Investigator Responsibilities
- Investigator Responsibilities
- Clinical Trial Design
- Protocol Design
- CRF Design
- Essential Documents in Clinical Research
- IND Application
- Clinical Study Report
- NDA Submission
- Informed Consent Process & Documentation
- Site Selection & Pre-study Visits
- Site Initiation
- Subjects Recruitment & Retention Plan
- Site Contracts & Budgeting
- Routine Site Monitoring
- CRF Review & Source Data Verification
- Adverse Event Reporting
- Drug Safety Reporting
- Drug Accountability
- Site Close-out
- Standard Operating Procedures for Clinical Research
- Sponsor Compliance & Audits
- Site Audit

Course Objectives :

- This course is intended to provide the necessary training for investigators and other senior site personnel, to better understand the regulations regarding clinical research in human subjects, and a better understanding of roles and responsibilities in planning and conducting clinical trials. The program also covers the regulatory aspects as well