cliniminds™
Institute of Health Sciences Training & Management
An ISO 9001:2008 Certified Academy

Assuring and Advancing Quality in Clinical Research Education since 1965

Post Graduate Diploma in Clinical Trials Quality Assurance, Auditing & Inspections

Clinical Trials in India have increased exponentially in number over the last decade. The increased business has brought into sharp focus the need to manage quality while conducting clinical trials. Quality in clinical research needs to be rigorously maintained by all the stakeholders of the clinical trial process. This includes the ethics committees, investigators and sponsors alike. Upon completion of the program, students would be able to understand the concepts of quality assurance in clinical trials, process and implications of Audits & Regulatory inspections and the issue of Frauds and misconduct. The program is practical in nature and students would be able to apply the knowledge in the work environment as well.

Program Details **:** The program would cover

Module-I

Introduction to QC, QA & Audits

- Introduction to Quality in Clinical Research
- Process Mapping in Clinical trials
- QA and QC in Clinical Research
- QA Activities
- QA Planning
- QA SOPs
- Practical exercises and Interactive sessions- Designing a process Map etc
- Tools of Audits
- Auditors - Who and What are they?
- Preparing for an Audit
- Conduct of an Audit
- CRO Audit
- Practical Case Scenarios in Audits

Module-II

Regulatory Inspections

- FDA Inspections- Preparation, Conduct, Reporting and Recording of Inspections
- EMEA Inspections- Preparation, Conduct, Reporting of Inspections
- MHRA Inspections- Preparation, Conduct, Reporting of Inspections
- ANVISA Inspections
- IEC/IRB Inspections
- DCGI Inspections
- Conduct of a Mock inspection
- Differences between FDA and EMEA Inspections
- Frauds, Misconduct and Errors
- Practical Scenarios in Regulatory Inspections

Disclaimer - This course brochure is for the purpose of creating an awareness about the program and career options. The exact information on course structure would be given to you at the time of orientation, and may vary from this brochure.

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Mode : Online/Distance Learning

Duration : 6 Months

Eligibility : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, Graduate/Post Graduate Degree in Life Sciences, Mathematics, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and Hospitals.

Methodology : Printed Training Modules; Online e-learning System

Examination : Online MCQs

Certificate : Certificate would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Pharmaceutical Society of India.**

Accreditation : Accreditation would be awarded upon successful completion of the program. Program is Certified & Accredited by **Accreditation Council for Clinical Research Education**, **US.**

Job Assistance : Placement support would be provided to the successful candidates. CVs of successful candidates would be forwarded to relevant organization.

Fee payment : Fee Payable by Cash, Cheque/Bank draft in the name of **"TENET HEALTH EDUTECH PVT LTD."** payable at Delhi. Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.

International Payments : Through Debit/Credit cards using Paypal or wire payment through banks

Course Objectives :

- To provide a comprehensive introduction to the clinical research process, conduct & management of clinical trials.
- Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate and other key positions.
- Become more familiar with roles/jobs as part of the study team.
- Extensive Knowledge & application in different aspects of Clinical Research.

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