Certificate in Good Clinical Practices

(GCP) is the international ethical, scientific and practical standard to which all clinical research is conducted. Compliance with GCP provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable. This certificate program is aimed at improving the conceptual knowledge of the participant for Good Clinical Practices and resolving any dilemmas that a working professional may face regarding the application of GCP guidelines at his workplace. Successful performance in this program implies that the participant has in-depth knowledge and clear understanding of industry guidelines and regulations. The training has been carefully designed to introduce the attendee to various aspects and basics of GCP, its need and benefits in assuring the ethical and scientific integrity of clinical trials. GCP compliance provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible. Several specialized topics have been added to guide the participant through ICH GCP regulations, compliance needs, comparison of Indian GCP guidelines vs. ICH GCP guidelines etc.

Program Modules

Module-1

Introduction to Drug Development and Clinical Trials

- Glossary/wordlist
- Steps of Drug Development Process
- Clinical Trial Phases and Design
- Functions of Clinical Trials
- Ethical evolution, Belmont Report
- Evolution of FDA and ICH guidelines

Module-2

- **Regulations in Clinical Research**
  - ICH GCP
  - Indian GCP
  - Biomedical Guidelines of India, ICMR
- **Essential Documents**
  - Understand Investigator's Brochure
  - Protocol Types and Designs
  - Informed Consent Documents and the process

Program Modules

Module-3

Research Site Management function 1

- Site Selection process
- Risk-based Approach
- Case Report Forms (designing and use)
- Site Initiation process
- Subject screening, recruitment and retention
- Bio-Analytical Overview Training
- Site Monitoring
  - Protocol compliance and deviation
  - AE/SAE forms and its reporting process
  - Compliance for Risk-based Monitoring

Module-4

Research Site Management function 2

- IMP/Drug inventory management
- Site regulatory document management
- Site Monitoring and Audit Function
- Scientific integrity, fraud and misconduct (GDPR, Indian Regulatory, HIPPA)
- Site closeout, return of IMP/Drug and Trial Record keeping
- Final report preparation and submission
- Handling of FDA and other regulatory inspections

Module-5

Data Management and advance Trial Management Functions

- e-clinical Trial and Data Management
- Data query and its resolution
- Data integrity and ICH guidelines
- Leadership functions at Trial Site
- Evaluating evidence-based interaction

Program Modules

Module-6

Orientation to Clinical Database Management and Pharmacovigilance

- Overview of software system in use for clinical database and record keeping
- Introduction to PVPI
- Introduction to E2A and E2F

Module-7

- Dissertation

Eligibility: Any Graduation/ B.tech/ B.Sc. in Microbiology/ Life Sciences/ Botany/ Zoology/ Food Science/ Food Technology/ BE/ B.Pharma/ MBBS/ BDS/ BHMS/ BUMS/ BAMS or any other discipline. Diploma holders are eligible for our Executive Diploma, Industry Certificate, and Certificate Programs.

Program Duration: 1 year (Post Graduate Diploma), 6 months (Executive Diploma)

Complementary courses:

1. Microsoft Excel and Word (Required skills to prepare the reports)
2. Preparation of CV and interview questions