ALCHEMY
Clinical Research Services
Transforming Research ...

# Good Clinical Practice

ICH

# CORPORATE TRAINING PROGRAM

www.alchemyclinical.in

The pharmaceutical industry is currently undergoing a large number of regulatory changes. Individuals that are involved in research will be directly affected. As we carry out our duties there is always the risk of compromising the data quality that we generate and the risk of breaching the various codes of ethics. An understanding of the principles and background of Good Clinical Practice are critical to ensuring credible data, high quality, and ethical research. This abridged course provides a demonstration of the GCP: ICH Good Clinical Practice (ICH-GCP).

## For Whom?

- ✓ **Investigators**
- ✓ **Ethics Committee**
- ✓ **Site Staff**
- ✓ **CRO Staff**
- ✓ **IT Professional**

## Duration:

**Basic Training**
**06 Hrs**

**Advanced Training**
**08 Hrs**

## Learner Outcomes

- Understand and apply the ICH Good Clinical Practice (GCP) and local regulatory guidelines for good clinical practice in the conduct of clinical trials
- Understand the QA-GCP-QC relationship
- Enable participants to appreciate the individual GCP responsibilities, quality management responsibilities, and know the consequences of failure to comply with the GCP Regulations
- Learn essential skills for effective SOP writing and GCP auditing
- Understand the importance of good documentation practices and record keeping
- Build networks with peers and professionals within the industry

# The GCP Training Package

Our GCP training package includes an introduction to GCP, targeted training, and focused risk-based learning. Learners get a basic knowledge of the topic, learning about the history of GCP, the Declaration of Helsinki, GCP principles, and the basics of roles and responsibilities. GCP training programs covers:

- ✓ Principles of ICH GCP
- ✓ History and purpose of GCP
- ✓ Roles and responsibilities of clinical research staff
- ✓ Ethics committees
- ✓ Essential documentation
- ✓ GCP sponsor responsibilities
- ✓ ICH GCP requirements and their impact on the role of the sponsor
- ✓ Awareness of the proper procedures, systems, and regulatory requirements in clinical research
- ✓ GCP for investigators
- ✓ ICH GCP requirements and their impact on the role of the investigators
- ✓ Strategies for ensuring adherence to the protocol
- ✓ Communication with the ethics committee
- ✓ Informed consent
- ✓ Drug accountability
- ✓ Safety reports

# Corporate Training Programs

**Alchemy offers corporate training services in the areas of clinical research for the Pharmaceutical, Clinical Research, IT and Biotechnology sectors.**

**The main objective of our corporate training program is to impart knowledge based on the changing environment in the pharmaceutical, clinical research and biotechnology industries.**

**We offer customized onsite training programs in the areas of Basic and Advanced GCP/ GLP/Clinical Monitoring/ Pharmacokinetics/IRB Training/ Validation/ 21 CFR Part 11 etc.**

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