GOOD CLINICAL PRACTICE (GCP) INSPECTORATE TRAINING PROGRAMME

To organize accredited Good Clinical Practice (GCP) training programmes for GCP inspectorate in accordance to national and international laws/ rules/standards guidelines. Following are the objectives of a GCP trainings:

- Ensure the rights, safety and well-being of study subjects have been protected.
- Determine whether the trial was conducted in accordance with applicable regulatory requirements, ethical standards and Pakistan Guidelines for Good Clinical Practice or otherwise.
- Determine whether the data submitted in the dossier are credible and accurate
- Assure the integrity of scientific testing and study conduct
- Report corrective action to ensure compliance and enforcement actions when deemed necessary.

List of trainings for GCP inspectorate is given below.

1. Overview of DRAP Act, 2012 relevant National and International Clinical Trial Rules, Regulation and Guideline Requirements.
2. Training on Good Clinical Practices (ICH and DRAP)
3. Introduction to the Principles and Practice of Clinical Research (IPPCR)
4. How to conduct GCP inspection / Audit
5. Clinical Trial Management and Monitoring of Clinical Trials to GCP
6. Managing Vendor/CRO Oversight to Comply with GCP
7. Data Integrity
8. Risk Management for Clinical Trials
9. Clinical Quality management System (QMS)
10. CAPA (Corrective and Preventative Action) for GCP Compliance
11. Ethics committees
12. GCP for sponsor
13. GCP for investigators
14. Role of Contract Research Organization (CRO)
15. ICH GCP requirements and their impact on the role of the investigators
16. Strategies for ensuring adherence to the protocol
17. Informed consent
18. Drug accountability
19. Safety and ADR reporting.