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"My Learning Life"

CLINICAL RESEARCH

CERTIFIED
ISO
9001:2015
COMPANY

Good Clinical Practice

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials.

GCP provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial human subjects are respected and protected.

Importance of GCP

The importance of GCP lies in the question 'why' and 'how' GCP trials came. To know the answer to this, we must look into the historical background that led to the formulation of GCP guidelines in the United States & Europe and to the formation of ICH. The events that led up to the culmination of the ICH - GCP guidelines brought forth public awareness that there was a need to control and regulate clinical trials dealing with drugs and human subjects.

The violation of human rights played a large role and that is why the Declaration of Helsinki and The Nuremberg Code remained as the framework of the present guidelines. The ICH-GCP guidelines are therefore considered the 'bible' of clinical trials and have become a global law which safeguards humanity as we know it today.

GCP Regulations

GCP follows the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) of GCP guidelines. GCP enforces tight guidelines on ethical aspects of a clinical study.

High standards are required in terms of comprehensive documentation for the clinical protocol , record keeping, training and facilities including computers and software. Quality assurance and inspections ensures that these standards are achieved. GCP aims to ensure that the studies are scientifically authentic and that the clinical properties of the investigational product are properly documented.

GCP guidelines include standards on how clinical trials should be conducted, defines the roles and responsibilities of institutional review boards, clinical research investigators, clinical trial sponsors and monitors.

Purpose of GCP

GCP describes the ethical and scientific aspects of a clinical trial and expressed in popular terms, GCP is the clinical trials "ISO standard". The purpose of this quality standard is to ensure that the trial subject's rights, safety and well-being are protected as described in the Declaration of Helsinki and to support clinical development of new medicines for patients in an ethical, effective and cost-effective way.

Comparison between GCP and other Indian Guidelines

India has been globally recognised as a nation that offers unique and distinct opportunities for carrying out clinical trials due to the existence of a large patient population, well experienced investigators and leading medical institutions along with the added benefit of low cost per patient used in contrast with the developed countries.

Nonetheless, changing times necessitated the establishment of our own Indian guidelines for GCP in order to provide a steady quality to clinical research studies initiated all over the country. Working towards this goal, an expert committee was set up by the CDSCO (Central Drugs Standard Control Organization), which provided able support by clinical experts from different parts of the country to formulate the first recognised document for GCP in India in 2001, which was tailored according to Indian requirements.

The DTAB (Drug Technical Advisory Board), the highest technical body as per the Drugs and Cosmetics Act, strongly endorsed the adoption of these GCP guidelines by the pharmaceutical industry to help and carry out well organised clinical studies in India.

These guidelines were constituted keeping in mind already well established and documented GCP guidelines like WHO, USFDA, ICH-GCP and the EU GCP guidelines. Apart from these, inspiration was also drawn from the ICMR (Indian Council of Medical Research) guidelines for Biomedical Research on human beings.

Regulators perspective for GCP Regulations

Regulatory inspections are important to evaluate the integrity of the data submitted to Health Authorities (HAs) protect patient's safety and assess adequacy of site/sponsor quality systems. Inspections generally occur after submission of data for marketing approval of an investigational drug.

In recent years, there has been a significant increase in number of inspections by different HAs, including in India. The assessors/inspectors generally do a thorough review of the site data before inspections.

All aspects of ICH-GCP, site infrastructure and quality control systems are assessed during the inspection. Drug development is being globalized and number of patients enrolled in studies are increasing who are submitted as a part of applications and those can come from all over the world. Because of the steep increase in research activity in the country, inexperienced sites, more stakeholders, increased efforts will be required to ensure continuous quality and compliance. HAs have also made clear that enforcement will be increased with swift, aggressive and effective.

Course Description

Clinical Research is a branch of healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

Clinical Research is the study of health and illness in people. Clinical Research describes many different elements of scientific investigation. It involves human participants and helps translate basic research (done in labs) into new treatments and information to benefit patients. Clinical trials as well as research in epidemiology, physiology and pathophysiology, health services, education outcomes, food, cosmetics, lifestyle products and mental health can all fall under the Clinical Research umbrella.

This programme is targeted towards imparting theoretical as well as practical knowledge of Good Clinical Practice to Candidates. After completion of the course, participant is expected to have in-depth knowledge and better understanding of industry guidelines, regulations, regulatory bodies, compliance and prospects. The modules have been compiled to introduce the attendee to various aspects and basics of GCP, its need and benefits in assuring quality of clinical trial. Several specialized modules have also been added to guide the Candidate through GCP regulations, compliance needs, comparative GCP, rules of India and other countries.

Module 1

- Introduction to Drug Development and Clinical Trials
- Steps for Drug Development Process
- Phases and Functions of Clinical Trials
- Ethical Evolution, Belmont Report
- Evolution of FDA and ICH guidelines
- Good Clinical Practice, FDA regulations
- Indian Good Clinical Practices

Module 2

- Biomedical Guidelines of India, ICMR
- Roles and responsibilities of Sponsor, Investigator and IRB
- Understand Investigator's Brochure
- Protocol Types and Designs
- Informed Consent Document

Module 3

- Research Site Management Function 1
- Site Selection Process
- Site Initiation Process
- Screening, Recruitment and Retention
- Protocol Compliance and Deviation
- Case Report Forms
- AE/SAE Forms and Reporting

Module 4

- Research Site Management Function 2
- IMP-Drug Inventory Management
- Site Regulatory Document Management
- Site Monitoring, Audit Functions
- Scientific integrity, Fraud and Misconduct
- Site Closeout, Drug Return, Records Function
- Final Reports, FDA and other HAs Inspections

Module 5

Data Management and Advanced Trial Management Functions

- e-Clinical Trials, Data Management
- Data Query Resolution
- Data Integrity and ICH guidelines
- Leadership Functions at Trial Site
- Evaluating Evidence based Interaction
- Compliance for Risk based Monitoring

Module 6

Orientation to Clinical Data Base Management and Pharmacovigilance

- Practical view of software system utilized in Database System
- Introduction to PVPI
- Introduction to E2A- E2F

Module 7

Analytical Hands on Training

- HPLC & LCMS Theory Training
- Demonstration of HPLC & LCMS
- Hands on Practical

Eligibility

The applicant must be a Graduate or Postgraduate in any discipline of Life Science, Pharmacy, Para Medical, Medical and Engineering Graduates (B.Tech and M.Tech in Biotech)

Course Duration

Programme duration is of 180 Hours

Programme Deliverables

- A comprehensive study material for all the modules in e-copies ensuring the needs of the candidate
- The accompanying training material is appropriately aligned with the current Industries expectations
- Assignments for all the programme modules for continuous evaluation and guidance. With Hand's on Practical Training on HPLC
- Interactive or recorded lectures on all key areas of the programme and giving flexibility to the candidates
- Assessment and evaluation for all the programme modules, in order to enhance the levels of competencies and skills of the participants leading towards the objective of application on the job
- At the end of each programme modules, the trainers shall obtain feedback from the participants using specially designed questionnaires
- Training on Soft Skills required for the industry like handling difficult situations and People, Trustworthiness and sustainability
- Self-development by way of Presentations, Group Discussions, Case studies, Role plays and Q&A sessions

Registration

The registration dates for this certification programme are announced regularly on digital platforms. For ongoing and Future dates Call **on 8318127735**

Programme Fees

Available on Request.

Certification

Pharma Knowledge Centre is exclusively providing the **Specialization Certification** to the students, to get highly paid placement on priority basis.

Placement Assistance & Corporate Relations

The Institute has partnered with many organizations for providing with placement assistance to its participants. Besides, it has a robust placement cell comprised of senior level Human Resources professionals and Talent Acquisition experts which maintains close links with business and industry. This cell is continuously engaged in promoting the employability of our participants and encouraging the concerned Human Resources department and Hiring Managers to recruit/hire our candidates for their vacant positions. The efforts of our placement cell also include helping with professional resume writing & interview skills.

Learning Objective

- The events that lead to the development of universal research ethics
- General principles and approaches to Clinical Research
- Regulatory requirements for application for Clinical Research
- The basic concepts and terms of Clinical Research
- Identify and classification for different types of trial design
- The purpose of ethics in research, what informed consent is and why it is necessary
- How high ethical standards, data quality and uniformity are maintained in a study
- Roles and Responsibilities of Stakeholders
- The basic concepts of designing a protocol
- The sections that should be included in a protocol
- Data management plan, the importance of collecting, recording and reporting adverse events
- The definition for the different categories of adverse events
- The mechanisms used for identifying these events, how they are evaluated when they occur and how follow-up may be carried out
- The necessity of assessing a causal relationship between the study intervention and the adverse event through pharmacovigilance

Functional Areas

- Clinics
- Hospitals
- Ethics Committee
- Pharmaceutical Companies
- Clinical Research Organizations
- Government Organizations
- Diagnostic Laboratories
- Information Technology
- Academic Institution

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