PhISTAR
Pharma Instinct Skill Training & Research

Pharma Instinct

ICH-GCP TRANING

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP)

Eligibility

BDS, BAMS, M.Pharma, M.Sc./M.Tech/M.Sc. in Biotechnology, Microbiology, Biochemistry, Molecular Biology, Ayurveda, Bioinformatics with good communication skills

DURATION: 1 Month Classes
Mode: Online / Offline Available

PROGRAMME MODULES

MODULE 1: INTRODUCTION TO ICH-GCP GUIDELINES

- Overview of ICH and its role in harmonizing global clinical trial regulations.
- The importance of Good Clinical Practice (GCP) in clinical trials.
- History and evolution of ICH-GCP guidelines.

MODULE 2: ETHICAL CONSIDERATIONS IN CLINICAL TRIALS

- The Declaration of Helsinki and its impact on GCP.
- Principles of ethics in clinical research.
- The role of ethics committees/institutional review boards (IRBs).

MODULE 3: INFORMED CONSENT PROCESS

- Understanding the informed consent process and its components.
- Ensuring voluntary participation and protecting vulnerable populations.
- Documentation and record-keeping for informed consent.

MODULE 4: ETHICS COMMITTEES/IRBS

- The role of Ethics Committees in clinical trials.
- Responsibilities and processes of Institutional Review Boards (IRBs).
- How ethics committees ensure the protection of trial participants' rights and well-being.
- Submission, review, and approval processes by ethics committees.

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