



# ICH-GCP TRAINING

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

**Eligibility:** BDS, BAMS, M. Pharma, B.Pharm, M.  
Sc./ M.Tech/ B. Sc./ B.Tech. in Biotechnology,  
Microbiology, Biochemistry, Molecular Biology,  
Ayurveda, Bioinformatics

**Duration:** 2 Months 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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