iLearn CRI
CLINICAL RESEARCH INSTITUTE

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COURSE SYLLABUS & FEES · 2026

ICH-GCP Certification Course in Pune

1-month ICH-GCP Certification Course in Pune at iLearn CRI covering E6(R3): the 13 core principles, informed consent, essential documents, ALCOA+ data integrity, and the New Drugs and Clinical Trials Rules 2019. ₹15,000 + GST (EMI available) with Offline & online batches for freshers and working professionals.

DURATION	MODE	FEES	EMI
1 month	Live online & classroom (Pune)	₹15,000 + 18% GST	Available

Eligibility

B.Pharm or M.Pharm graduates
B.Sc / M.Sc in Life Sciences, Biotechnology, Microbiology, Chemistry
BDS, MBBS, BHMS, BAMS, BPT graduates
Nursing graduates (B.Sc Nursing, GNM)
Working professionals in clinical research, CROs, hospitals, or sites who need a recognised GCP certificate

Complete syllabus, module by module

01 Foundations & History of GCP

History and purpose of Good Clinical Practice
The Declaration of Helsinki and its ethical foundations
What ICH-GCP E6(R3) is and how it updates E6(R2)
The 13 core principles of ICH-GCP

02 Roles & Responsibilities

Sponsor responsibilities and oversight obligations
Investigator responsibilities and delegation of duties
Monitor (CRA) responsibilities and monitoring approaches
IRB/IEC composition, functions, and responsibilities

03 Informed Consent & Ethics in Practice

The informed consent process, elements, and documentation
Consent in vulnerable populations and emergency situations
Re-consent following protocol or safety updates
Ethical review, approvals, and continuing oversight

04 Essential Documents & the Trial Master File

The essential document set and why each is required
Structure and maintenance of the Trial Master File (TMF)
Protocol, Investigator's Brochure, and source documentation
ALCOA+ data integrity principles in practice

05 Protocol Compliance & Safety Reporting

- Protocol compliance, deviations, and corrective actions
- Adverse events, serious adverse events, and SUSAR reporting
- Safety reporting timelines and sponsor/investigator duties
- Quality management and risk-based thinking under E6(R3)

06 Audits, Inspections & Indian Regulations

- Sponsor audits and regulatory inspections — how to prepare
- Inspection readiness at the site and common findings
- The New Drugs and Clinical Trials Rules 2019 (India)
- CDSCO oversight and how GCP maps to Indian requirements

Career outcomes

ROLE	AVERAGE CTC
Clinical Research Coordinator (CRC)	₹ 3.0–4.0 LPA
Clinical Trial Assistant (CTA)	₹ 3.0–4.0 LPA
Site Coordinator	₹ 3.0–4.0 LPA
Research Nurse	₹ 3.5–4.5 LPA
Ethics Committee Coordinator	₹ 3.5–4.5 LPA

Placement support built in

100% placement assistance for every student: resume calibration, mock interviews with practicing professionals, and direct introductions to 50+ pharma & CRO hiring partners. Average starting CTC across placements: ₹4.2L. Separate live online and classroom batches — same curriculum, same fees, same support.

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