Eligibility for the Course?

- B. Pharm, M. Pharm, Pharm D, M.Sc (With any Life Science Disciplinary) Pursuing or Completed Students
- Academician
- Industry Person

Registration Details

Course Fees
30000 + GST

Course Duration
3 Months | 250 Hr

Last Date for Registration
29th March 2025

Course Commencing from
7th April 2025

Registration Link
https://shorturl.at/Tqqhw

Earn 16 academic credits hours
towards your degree with
our Clinical Research Certificate Course, jointly offered
by Cliantha Academy & CCE GTU.

For Any Query Contact
Mr. Jay Soni
Executive - BD & Trainer
Cliantha Academy
+91 93167 33464 | academy@cliantha.com

For Registration, scan here

Patron

Mr. Naveen Sharma
CEO, Cliantha Research

Ms. Arpana Prasad
AVP, Global QA/QC, Cliantha Research

Convenor

Mr. Nayan Prajapati
GM & Head Training
Cliantha Research & Cliantha Academy

Course Coordinator

Mr. Jay Soni
Executive - BD & Trainer
Cliantha Academy

GTU-CCE Coordinator

Prof. Manish Panchal
Assistant Professor, GTU-GSET

Resource Person

**Mr. Nayan Prajapati, Mr. Jay Soni
Dr. Anokhi Shah, Ms. Hina Prajapati
Mr. Hardik Panchal**

Cliantha Academy
2nd Floor, 17, Sigma Corporates, Sindhubhavan road, Bajarang Cross road,
opp. Courtyard Marriott, Ahmedabad, Gujarat 380054

📞 **+91 9316733464**

🌐 **www.cliantha.com**

✉️ **academy@cliantha.com**

**GUJARAT TECHNOLOGICAL UNIVERSITY
CENTRE FOR CONTINUING EDUCATION**
(GTU-CCE) CERTIFIED

Certificate Course on Clinical Research

cliantha academy
(An Educational Initiative by Cliantha Research)

Create, Learn, Inspire with Cliantha Academy
– A Journey of Excellence

About Cliantha Research

Cliantha Research, full-service Clinical Research Organization (CRO), provides comprehensive and integrated offerings in Early Phase (BA-BE & Phase I), Late Phase (II-IV), Respiratory, Tobacco Research, Dermatology, Consumer Research, Research Lab, IVRT, Biometrics, Medical Services, Environmental Exposure Chambers (EECs).

Cliantha now has presence in 3 countries along with a strong team of 1500+ professionals. Some of the key regulators, such as the USFDA, GCC, EMA, AGES, ANSM, ANVISA, AMPS, MCC South Africa, Health Canada, Malaysia NPRA, DCGI, CAP, NABL, Turkey MOH,Thailand MoPH and others have successfully inspected Cliantha across the globe.

About Cliantha Academy

Cliantha Academy, an educational initiative by Cliantha Research, bridges the gap between academia and industry by offering specialized clinical research courses. Focused on practical applications, it equips students with the skills and knowledge needed to thrive in the evolving healthcare and research sectors. Beyond high-quality education, the academy provides placement assistance, ensuring a strong career foundation in clinical research. By combining academic excellence with industry insights, Cliantha Academy shapes future professionals for success in clinical trials and research.

Topics to be covered in Course

- Drug Development and role of regulated Clinical Research
- Healthy Volunteer Clinical Trial Setup and Study Flow
- Patient based Clinical Trial Setup and Study Flow
- The Stakeholders in Clinical Trials
- Roles and responsibilities of Sponsor, Ethics Committee, Investigator/Sites and Regulatory Agency
- Clinical Trial Study Design & Randomization
- Essential Documents & Study Feasibility Assessment
- SQV, Site Selection & Initiation, Site Monitoring, Site Close Out
- Ethics Committee/ Regulatory pathway
- Investigational Products - Managing, Handling & Accountability
- Good Clinical Practice (ICH E6) & Good Documentation Practices
- New Drug Clinical Trial Rule (NDCT) & ICMR Guideline
- Basic Orientation to Regulatory Bodies (DCGI, EMA, MHRA, USFDA)
- Trial master file –Set up & Maintenance, Practical Aspects
- Informed Consent Procedure & Case Studies
- Patient/Participant Recruitment, Retention, and Compliance
- Guidelines for Reporting of AE/SAE
- Audit Plan, Audit & Audit Report
- Overview of Clinical Data Management (CDM) in Clinical Trial
- CTRI & Importance of Various Regulatory Forms
- Various Job Role in CT and Roles and Responsibility
- Clinical Trial Site Visits & Industry Expert Sessions
- Communication & Public Speaking Workshop
- Career Counseling

Expert HR Lecture | Mock Interviews | Personal Mentoring
Social Media Guidance | Interview Do's and Don'ts
CV Preparation | Email Etiquette | MCQ based final Exam
- Placement Assistance

About Gujarat Technological University

Gujarat Technological University is a premier academic & research institution which has driven new ways of thinking since its 2007 founding, established by the Government of Gujarat vide Gujarat Act NO. 20 of 2007. Today, GTU is an intellectual destination that draws inspired scholars to its campus, keeping GTU at the nexus pf ideas that challenge and change the world. GTU is a State University with 486 affiliated in colleges its fold operating across the state of Gujarat through its Five zones at Ahmedabad, Gandhinagar, Vallabh Vidyanagar, Rajkot and Surat. The University caters to the fields of Engineering, Architecture, Management, Pharmacy and Computer Science. The University has about 4,00,000 students enrolled in a large number of Diploma, Under Graduate, Post Graduate Programs along with the robust Doctoral Program.

Objective of GTU-CCE Course

- To bridge the gap between industry expectations and academic outcomes through Theoretical and Practical training.
- To upskill freshers by instilling real-time practical abilities, enhancing their integration into the clinical research industry.
- To create skilled professionals equipped with practical skills essential for a successful career.

Outcomes of GTU-CCE Course

- Industry-Ready Professionals
- Hands-on Training & Practical
- Certifications & Credibility
- Strong Networking Opportunities.
- Higher Employability
- Global Opportunities

Why join this Course?

- Equips students with practical knowledge and hands-on experience to meet industry expectations.
- Comprehensive training in ICH-GCP, NDCT 2019, ICMR, and other guidelines ensures students are industry-ready worldwide.
- Opens doors to roles like CRA, CRC, CTA, QA, QC, Medical Writer, and more in CROs, pharma companies, and hospitals.
- Enhances communication, leadership, teamwork, and problem-solving skills, making students confident professionals.
- Resume building, interview preparation, and direct job referrals to top clinical research organizations and hospitals.