

### Resource Persons

**Dr. Manoj Karwa**  
HOD,  
Clinical Trials and Pharmacovigilance,  
Auriga Research Pvt. Ltd.

**Mr. Shailendra Jha**  
HOD, Medical Research,  
Kokilaben Dhirubhai Ambani Hospital  
and Medical Research Institute, Mumbai.

**Dr. Hardik Soni**  
AGM Research and Development,  
Vasu Research Centre, Vadodara.

**Dr. Rikin Patel**  
Global Clinical Research Project Manager,  
Veeda Clinical Research Ltd., Ahmedabad

**Dr. Dipal Rana**  
Manager, Pharmacovigilance,  
Lupin Pvt. Ltd., Mumbai

**Dr. Manoj Swaminathan**  
Pharmacovigilance Expert, Mumbai

**Dr. Shivani Desai**  
Manager Clinical Operations,  
Serum Institute, Pune

**Dr. Jalaram Thakkar**  
Manager, PPED, Meril Endo Surgery Pvt Ltd., Vapi

**Dr. Ajit Singh**  
Co-Founder And CEO Climed Research Solution, India

**Mr. Amish Gandhi**  
Pharmacovigilance Officer Team Lead,  
Ahmedabad, Gujarat

**Mr. Prit Desai**  
Pharmacovigilance Officer,  
Lambda Therapeutics Research Ltd., Ahmedabad

**Mrs. Saloni Desai**  
Safety Associate, IQVIA,  
Bengaluru, Karnataka

### Chief Patrons

**Rtn. Rajjubhai Shroff**  
Chairman, ROFEL Trust

### Patrons

**Rtn. Ashis Roy**  
Secretary Trustee, ROFEL Trust

**Rtn. Bharat Patel**  
Trustee, ROFEL Trust

**Rtn. Praful Dewani**  
Trustee, ROFEL Trust

**Rtn. Ujjwal Kakaria**  
Trustee, ROFEL Trust

**Rtn. Dipak Shah**  
Trustee, ROFEL Trust

**Rtn. Rakesh Patwari**  
Trustee, ROFEL Trust

### Convenor & Course Director

**Dr. Arindam Paul**  
Professor & Principal

### Course Coordinators

**Dr. Ankit Merai**  
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### GTU-CCE Coordinator

**Prof. Mahesh Panchal**  
Assistant Professor, GTU-GSET

### Contact Us

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ROFEL Shri G. M. Bilakhia College of Pharmacy, Vapi

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



**SHORT TERM CERTIFICATE COURSE**  
**on**

**"CLINICAL RESEARCH AND PHARMACOVIGILANCE"**  
**1st BATCH STARTING FROM 12/03/2023**



**ORGANIZED BY**



**ROFEL SHRI G. M. BILAKHIA COLLEGE OF PHARMACY, VAPI**  
ROFEL NAMDHA CAMPUS "NAMDHA ROAD-VAPI[W]" 396191, GUJARAT, INDIA  
CONTACT: +91 9727723722|42|62. Website: www.rofelpharmacy.ac.in

**NAAC Accredited B++ Grade Institution**  
**An ISO 29990:2010 & ISO 2009:2015 Certified Institution**  
(Experience Innovation in Education)

## About Trust

ROTARY CLUB OF VAPI - a Member Club of Rotary devoted to social work; established in 1985 an Educational Trust named 'ROTARY FOUNDATION FOR EDUCATION AND LEARNING' popularly known as 'ROFEL' to provide educational facilities in the region at all levels. In the initial years, the Trust organized and awarded scholarships to local students to enable them to study outside Vapi in various disciplines, ranging from Engineering and medicine to business administration, arts and commerce. The Trust started the first college (Arts and Commerce College) in Vapi in 1989, followed by many educational institutions as follows:

(A) ROFEL Shri G. M. Bilakhia College of Pharmacy, Vapi.

(B) GIDC Rajju Shroff ROFEL Institute of Management Studies, Vapi.

(C) ROFEL Smt. C. D. Jhobalia College of Arts and Smt. I.S.R.

Achhariwala College of Commerce, Vapi.

(D) Sandra Shroff ROFEL College of Nursing, Vapi.

(E) GIDC Rajju Shroff ROFEL Institute of Management Studies (BBA) Programme, Vapi & ROFEL Shri G. M. Bilakhia College of Applied Sciences (BCA), Vapi.

## About Institute

ROFEL Shri G. M. Bilakhia College of Pharmacy is a modern temple of learning founded in 1999 by ROFEL Trust where quality education is more than a philosophy. It is one of the premier pharmacy colleges, imparting quality pharmaceutical education and training for more than two decades offering undergraduate and postgraduate courses in Pharmacy. The foundation of the college was laid from the generous donation from well known Industrialist Shri G. M. Bilakhia. More than 1500 Pharmacists (B. Pharm and M. Pharma graduates) of ROFEL now hold prominent positions in industry and academia, both in India and Abroad. The College is located at ROFEL Namdha Campus which is about 1.5 km from Vapi Railway Station and about 2 km from Vapi GSRTC Bus Stand. The ROFEL Namdha campus is about 5 km from GIDC-Vapi Gunjan Highway Cross road on Vadodara-Mumbai # NH-48

## 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 of ideas that challenge and change the world. GTU is a State University with more than 450 affiliated colleges in 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

## Objectives of GTU-CCE Certified Short-Term Course

- To understand basics of pharmacology and pharmacy in clinical research.
- To understand and evaluate the novel signal (ADR) from the cases that have been reported.
- Analysis the benefit-risk ratio of commercially available drugs.
- The evidence-based information on the pharmaceutical safety.
- To assist regulatory bodies in making decisions on the use of drugs.
- To reduce risk, it is important to inform diverse stakeholders on the safety of using medications.
- Generating expertise in pharmacovigilance operations.

## Outcomes of GTU-CCE Certified Short-Term Course

- Knowledge on molecular clinical research, chemical clinical research, forensic clinical research, etc.
- Knowledge on Clinical trial compliance and quality assurance.
- Participants will get idea about Pharmacovigilance, ADR, regulations in pharmacovigilance.
- Participants will learn about herbal and medical device vigilance.
- Knowledge on inspection and compliance of Pharmacovigilance.

## Topics to be Covered

- Drug Development process
- Documentation of CTA/NDA dossier
- Advancement in Contract Research Organization.
- Molecular Clinical Research, Chemical Clinical Research, Forensic Clinical Research, Computational Clinical Research, Chrono-Clinical Research etc.
- Clinical Trial Designing, Clinical trial documentation, Clinical Trial data and safety monitoring
- Pharmacovigilance- Safety data generation, drug dictionaries and coding, Ecopharmacovigilance, CIOMS in Pharmacovigilance
- Pharmacovigilance of Herbal drugs, Medical device, Material vigilance and Hemovigilance.
- Pharmacovigilance compliance and Inspections, Aggregate safety report

## Why Participants should join this Course...?

- The course is designed to provide total overview and skill required in the field of clinical research and pharmacovigilance.
- Will help students, graduates and professionals to upgrade and develop their knowledge about clinical trials, data managements, pharmacovigilance, regulatory issues and other major aspects of pharmacovigilance.
- Will increase the career prospects of participants in the field of Clinical Research such as Clinical Research Coordinators, Clinical Research Associate and Pharmacovigilance experts.

## Eligibility for Participation

Of Pharmacy, Medical, Science and Life Science courses Students, Graduates, Post-Graduates, Research Scholars, Professionals from Pharmaceutical Industries, Hospitals, HealthCare Organisation and Academia.

## Registration Details

**Registration fees :** Rs. 1800/-

**Registration Link :** <https://forms.gle/cgsrBu6X7KDN92Nu8>

**Last Date for Registration :** 04/03/2023

**Course Commencing From:** 12/03/2023

**Duration:** 36 Hours  
(Online Mode via Google Meet)

N.B:

1. **Attendance** is compulsory for all sessions.
2. **Minimum** passing marks should be obtained in evaluation test to get course certificate
3. **Classes:** In online distance learning mode
4. **Examination:** Online ( MCQ/ Theoretical, presentation)
5. **Certification eligibility:** The certificate will be provided only after successful completion of the course (examination/ presentation) by Gujarat Technological University
6. **Attendance** will be recorded in each session and considered mandatory.

## Payment Details

**Bank Name:** Bank of Baroda

**A/c Name:** ROFEL Shri G. M. Bilakhia College of Pharmacy

**A/c No :** 02370100019077

**IFSC Code :** BARB0VAPIXX  
(Fifth Character is ZERO)

**Branch :** Vapi Town Branch