

# ROFEL Shri G M Bilakhia College of Pharmacy

*Experience Innovation in Education*

Approved by Pharmacy Council of India (PCI) and Affiliated to GUJARAT TECHNOLOGICAL UNIVERSITY (GTU), AHMEDABAD  
An ISO 9001:2015 & ISO 29990:2010 Certified Institution



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## Our Highlight of Month



**Congratulations to our Student**  
**Ms. Anali Ashokbhai Patel (M.Pharm Sem 3)**  
**for securing Gold Medal at GTU level Inter zonal (1 to 5)**  
**in Powerlifting competition**  
**Total weight lifted: 200 kg**



# INSTITUTE AFFAIRS

## Celebration of Azadi Ka Amrut Mahotsav

Our Institute ROFEL Shri G. M. Bilakhia College of Pharmacy, Vapi also became a part of this and celebrated Independence day 2022 with the theme of this journey of Azadi Ka Amrit Mahotsav. on 15th August 2022, Monday all staff members and students joined flag hoisting by the Chief Guest Rtn. Rakesh Patwari (Trustee – ROFEL Trust) Followed by the National Anthem at ROFEL, Namdha campus. At Pharmacy College Building, for students of Pharmacy college, A cultural programme was also commenced with various activities like Dance for Nation, Sing for Nation, Paint for Nation, Speak for Nation, Act for Nation and Human Pyramid under the guidance of - Dr. Arindam Paul [Principal] and Mrs. Harshida Patel [coordinator cultural activities]. The programme started with Lamp lighting by The Principal and invited guest Mrs. Bandana Paul.

The NSS cell of the institute also joined the celebration and a Tiranga Rally was also held under the guidance of Ms. Shreya Naik[coordinator – NSS activities].

In this celebration, almost 106 students and staff members joined the by their participation in various activities with full enthusiasm and patriotism. The event was concluded by National anthem.





# INSTITUTE AFFAIRS

## Sports Achievements



Gujarat Technological University organizes the inter-college Badminton tournament at J.P. pardiwala art and commerce college, Killa-Pardi, Valsad. on 17th August 2022. Our student Nikita Champaneri, M. Pharm Sem. 3, took part in a badminton competition. She performed admirably in the first two rounds, winning a place in the forthcoming inter-zonal badminton competition at the Sardar Vallabhbhai Patel Institute of Technology, Vasad, Gujarat.

Gujarat Technological University organizes the inter-college kabaddi tournament at Smt. BNB Swaminarayan College, Salvav, Vapi on 13th August ,2022. The girls' kabaddi team took first place and was chosen to compete at Shri Lalubhai Trivedi Institute of Engineering, Rajkot's next zonal level.



Gujarat Technological University organizes the Inter-college Powerlifting Men Women tournament at Naranala School of Industrial Management and Computer Science, Navsari on 23rd August 2022. During the selection process for powerlifting competitions, the squat, bench press, and deadlift have been used to evaluate candidates. Ms. Anali Ashokbhai Patel, M. Pharm Sem 3 performed an under 52kg powerlifting category. She had successfully lifted a total weight of 200 kg in the competition and got 1st rank and been successful in lifting a total weight of 200 kg in the competition and she got 1st rank and secured a gold medal.



# INSTITUTE AFFAIRS

## Article publication on

**RP-HPLC Method Development and Validation for Simultaneous Estimation of Isoniazid and Rifapentine in Synthetic Mixture by Patel Ankita Vinod Chandra, Dr. Alisha Patel in International Journal of Pharmaceutical Sciences Review and Research**



## Placement of our students

**ROFEL Shri G M Bilakhia College of Pharmacy**  
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(Experience Innovation in Education)

### PLACEMENT 2021-22

#### Congratulations

**SUBHAM PANDE**  
B.PHARM BATCH:2021-22



**S Kant**  
HEALTHCARE Ltd.

9727723742 | 9727723742 | 62 | rofelpharm@gmail.com  
B Pharm | M Pharm (Pharmacology) | M Pharm (Pharmaceutics)  
M Pharm (Pharm. Quality Assurance)  
ROFEL-NAMDHA CAMPUS, VAPI- NAMDHA ROAD, VAPI-396191 (GUJARAT)

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### PLACEMENT 2021-22

#### Congratulations

**NIYATI PATEL**  
B.PHARM BATCH:2021-22



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(Experience Innovation in Education)

### PLACEMENT 2021-22

#### Congratulations

**RAGINI PATEL**  
B.PHARM BATCH:2021-22



**exemed**  
pharmaceuticals

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## Upcoming GTU certified CCE course on Pharmaceutical Drug Regulatory Affairs

### Resource Persons

**Dr. Anil Kathirya**  
General Manager F&D,  
Amnol Pharmaceuticals, Ahmedabad, Gujarat

**Mr. Tejash Shah**  
Director,  
Bipham CMC Regulatory Affairs, GSK, London, UK

**Mrs. Kirti Kathirya**  
Founder and Director,  
KTK Technologies, Ahmedabad

**Mr. Hiren Bhagat**  
Sr. Manager,  
Zylus Lifesciences Ltd. Ahmedabad, Gujarat

**Mr. Hansal Gandhi**  
Regulatory Affairs Executive,  
JAMP Pharma Group, Ahmedabad, Gujarat

**Mr. Harshvardhan Bhalaria**  
Regulatory Affairs,  
Abbott Laboratories, Mumbai

**Mr. Vijay Satapara**  
Founder and CEO,  
Raid Pharma and Techno Consultancy Pvt. Ltd. Vadodra, Gujarat

**Mr. Umesh Dobariya**  
Associate Director,  
Saii Pharma and Techno Consultancy Pvt. Ltd. Vadodra, Gujarat

**Ms. Iva Dhuliy**  
Manager,  
Saii Pharma and Techno Consultancy Pvt. Ltd. Vadodra, Gujarat

**Mr. Pragnesh Donga**  
in Charge - Regulatory Affairs,  
Zylus Lifesciences Limited / Zylus Therapeutics Inc.,  
Ahmedabad

**Mr. Manoj Karwa**  
Head - CT and PI,  
Auriga Research Private Limited, Gurugram, Haryana

### Chief Patron

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

### Patrons

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

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

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

### Convenor

**Dr. Arindam Paul**  
Professor & Principal

### Course Coordinators

**Dr. Shuchi Desai**  
Associate Professor  
Mob: 972991641

**Dr. Hitesh Dalvi**  
Professor  
Mob: 9890881752

### GTU-CCE Coordinator

**Mr. Mahesh Panchal**  
Assistant Professor, GTU-UGET  
Head, GTU-CCE

### Contact us

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



### SHORT TERM CERTIFICATE COURSE ON PHARMACEUTICAL DRUG REGULATORY AFFAIRS



### —ORGANIZED BY—



**ROFEL Shri G M Bilakhia College of Pharmacy**  
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Rotary Foundation for Education and Learning (ROFEL) Trust  
An ISO 9001:2015 & ISO 29990:2010 certified institution  
ROFEL, Namdha campus, Vapi- Namdha Road,  
Vapi-396191, Gujarat  
Phone-91-9727723742, 9727723742  
Website- rofelpharm.ac.in

### About Trust

**TARY CLUB OF VAPI** - A Member Club of Rotary International devoted to social work, has established in 1970 an Educational Trust named **ROTARY FOUNDATION FOR EDUCATION AND LEARNING** popularly known as **ROFEL** to provide educational facilities in the region at all its levels. In the initial years, the trust organized and awarded scholarships to local students to enable them to study abroad. In recent years, the trust has started to study abroad students in various disciplines, ranging from engineering to medicine to business administration, arts and sciences.

### About Institute

**ROFEL Shri G M Bilakhia College of Pharmacy** is a center of learning founded in 1999 by ROFEL Trust. It is one of the premier pharmacy colleges in India, imparting quality pharmaceutical education and training for more than 15 years. The college is offering undergraduate and postgraduate education in Pharmacy. The foundation of the college was laid in the year 1999 by the Government of Gujarat. The college is situated in the field of Pharmacy, the age and its faculty are mainly focused in three areas - Education, Research, and Development. The college has rich resources to nurture the research aptitude of the students.

### Our Gujarat Technological University

Gujarat Technological University is a premier academic and research institution which has drawn new ways of thinking since its founding, established by the Government of Gujarat vide Gujarat Act No. 20 of 2007. Today, GTU is an educational institution that draws inspired scholars to its fold, keeping GTU at the vanguard of ideas that challenge the world. GTU is a State University with 400+ affiliated colleges in its field operating across the state of Gujarat through its five zones at Ahmedabad, Gandhinagar, Vallabhnagar, Rajkot and Surat. The University caters the fields of Engineering, Architecture, Management, Pharmacy and Computer Science. The University has about 10000 students enrolled in a large number of Diploma, Bachelor's, Post Graduate programs along with the post Doctoral program.

### Objectives of GTU-CCE Course

Upon completion of this course, it is expected that students will be able to:

- Understand new drug approval process, regulatory requirements for various countries, documentation related approval and post approval process, guidelines to conduct pre-clinical and clinical studies, audits and post approval changes.
- Understand various documents, its preparation, filing, checking and approval process required for regulatory aspects.

### Outcome of GTU-CCE Course

- Participants will learn the new drug approval process and its submission.
- Participants will learn about guidelines to carry out pre-clinical and clinical studies required for new drug approval.
- Participants will learn the process of submission of global documents like dossier, CTX, eCTD, CMC etc., audit process and post approval changes.
- Participants will get knowledge about various governing regulatory bodies across the globe.

### Topics to be covered

- Drug discovery and development
- Submission process of NDA, IND, ANDA
- Pre-clinical drug development and clinical trials
- Submission of global documents
- CTX and eCTD filing
- Inspection and audits
- Management of data integrity
- Governing regulatory bodies across the globe
- Demonstration of dossier preparation

### Why participants should join the course?

This course will increase the chances to get placements in Pharmaceutical industry.

- Certificate holder will get advantage to get placement in Regulatory Affairs department in industry.
- Participants will get certificate from GTU after successful completion of the course.

### Eligibility for participation

- B.Pharm, M.Pharm, M.Pharm or Pharm.D students or pass
- Students or passout B.Sc or M.Sc
- Professionals from Pharmaceutical industry and academia

### Registration Details

**Registration Fees** - Rs. 1500/-

**Payment Details:**  
Bank Name: Bank of Baroda  
Branch Name: Vapi Town  
Account Number: 0237010019077  
Account Name: ROFEL SHRI G M BILAKHIA COLLEGE OF PHARMACY  
IFSC: BARB0VAP00 (with character is zero)

**Registration Link:**  
<https://forms.gle/7ZavWm85FQ66eA>

**Last Date for Registration:** 05-09-2022

**Course Commencing From:** 05-09-2022

**Duration:** 36 hours (20 hours theory & 16 hours practical)  
Via online platform (every Saturday & Sunday)