

Resource Persons

Dr. Atul Kathiriya

General Manager F&D,
Amneal Pharmaceuticals, Ahmedabad, Gujarat

Mr. Tejash Shah

Director,
Biopharm CMC Regulatory Affairs, GSK, London, UK

Mrs. Kirti Kathiriya

Founder and Director,
K K Technolegal, Ahmedabad

Mr. Hiren Bhagat

Sr. Manager,
Zydus Lifesciences Ltd., Ahmedabad, Gujarat

Mr. Hansal Gandhi

Regulatory Affairs Executive,
JAMP Pharma Group, Ahmedabad, Gujarat

Mr. Harshvardhan Bhalara

Regulatory Affairs,
Abbott Laboratories, Mumbai

Mr. Vijay Satapara

Founder and CEO,
Isazi Pharma and Techno Consultancy Pvt. Ltd. Vadodara, Gujarat

Mr. Umesh Dobariya

Associate Director,
Isazi Pharma and Techno Consultancy Pvt. Ltd. Vadodara, Gujarat

Ms. Iva Dhuliya

Manager,
Isazi Pharma and Techno Consultancy Pvt. Ltd. Vadodara, Gujarat

Mr. Pragnesh Donga

In Charge – Regulatory Affairs,
Zydus Lifesciences Limited / Zydus Therapeutics Inc.,
Ahmedabad

Mr. Manoj Karwa

Head - CT and PV,
Auriga Research Private Limited, Gurugram, Haryana

Chief Patron

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

Dr. Arindam Paul

Professor & Principal

Course Coordinators

Dr. Shuchi Desai

Associate Professor
Mob- 9712951641

Dr. Hitesh Dalvadi

Professor
Mob- 8980881252

GTU-CCE Coordinator

Mr. Mahesh Panchal

Assistant Professor, GTU-GSET
Head, GTU-CCE

Contact us

E.mail-
rofelgtuccera1@gmail.com
ROFEL Shri G.M Bilakhia College of Pharmacy,
Namdha Road, Vapi

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

Managed by
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 9727723722 /42/ 62

Website- rofelpharmacy.ac.in

About Trust

ROTARY CLUB OF VAPI – a Member Club of Rotary International devoted to social work; has 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.

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 in India, imparting quality pharmaceutical education and training for the more than two decades, offering undergraduate and postgraduate course in Pharmacy. The foundation of the college was laid from the generous donation from well known Industrialist Shri G. M. Bilakhia. The college is involved significantly in Research & Development in the field of Pharmacy. The college and its faculty are mainly focused in three areas – Formulation Development, Analytical Method Development and Pharmacological Research. College has rich resources of faculty to nurture the research aptitude of the students.

About Gujarat Technological University

Gujarat Technological University is a premier academic and 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 486 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 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.

--To understand various documents, its preparation, filling, 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, CTD, 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
- CTD and eCTD filling
- Software of eCTD filling
- 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

--- D.Pharm, B.Pharm, M.Pharm or Pharm.D (students or passout)

--- Students or passout B.Sc or M.Sc

---Research scholars

--- Professionals from Pharmaceutical industry and academia

Registration Details

Registration Fees- Rs. 1800/-

Payment Details-

Bank Name- Bank of Baroda

Branch Name- Vapi Town

Account Number- 02370100019077

Account Name- ROFEL SHRI G.M BILAKHIA COLLEGE OF PHARMACY

IFSC- BARB0VAPIXX (*Fifth character is zero)

Registration link-

<https://forms.gle/Y2aVgWmBt8FQQ6GeA>

Last Date for Registration- 05-09-2022

Course Commencing From- 09-09-2022

Duration- 36 hours (30 hours theory & 06 hours practical)
Via online platform (every Saturday & Sunday)

