

Resource Persons

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Chairman, ROFEL Trust

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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

PHARMACEUTICAL QUALITY MANAGEMENT SYSTEM

3rd Batch Commences From 19/03/2023



ORGANIZED BY



ROFEL Shri G. M. Bilakhia College of Pharmacy

NAAC Accredited "B++" Grade Institution

An ISO 9001:2015 & ISO 2990-2010 Certified Institution

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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 Shri G. M. Bilakhia College of Applied Sciences, Vapi.
- (D) ROFEL Smt. C. D. Jhobalia College of Arts and Smt. I.S.R. Achhariwala College of Commerce, Vapi.
- (E) Sandra Shroff ROFEL College of Nursing, Vapi.
- (F) GIDC Rajju Shroff ROFEL Institute of Management Studies (BBA) Programme, Vapi.

About Institute

ROFEL Shri G. M. Bilakhia 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 decade 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 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 & 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

- To provide knowledge of pharmaceutical management system in all aspects to maintain quality standards and to facilitate continuous improvement of process performance and product quality.
- To develop an effective monitoring control in organization based on the performance as well as product quality.
- To coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.
- To provide understanding of concepts like What is Quality, Quality audit, Total Quality Management, Self inspection, Out of Specification, Out of Trade, Corrective and Preventive Actions,

Outcomes of GTU-CCE Course

- On completion of the course, the participants will be able to:
- Understand concept of vision, mission, quality objective and quality policy in a pharmaceutical organization.
 - Understand practical quality management aspects carried out at pharmaceutical industries.
 - Appreciate the importance of Quality system, to archive quality products.
 - Understand responsibility of personnel working in QMS, QA/QC and production department with respect to Pharmaceutical Quality Management systems.
 - Increase ability to solve cases of TQM, change management/ change control, deviations, OOS, OOT and CAPA.

Topics to be Covered

- Introduction to Quality, Mission and Vision statements
- Quality Objectives and Quality Policy, Cost of Quality Management
- Principles of Six-Sigma, ICH Q10
- Concept of Self-inspection, Quality Audit and Compliance
- Elements of Audit, Quality Audit check points in QMS
- Annual Product review, Batch Review and Batch Release
- Quality Testing Tools and Techniques for Root cause analysis
- Change control, Deviation
- OOS (Out of Specification)
- OOT (Out of Trend)
- CAPA (Corrective and Preventive Action)

Why Participants should join this Course...?

- This course will increase the chance to get placement in Pharmaceutical Industry.
- Certificate holder will have advantage to get placement in Quality Assurance/ Quality Control department in Pharma industry.
- Certificate will be given by GTU after Successful Completion of Course.
- These Certificate from GTU has equivalent credit to other GTU certificates.

Eligibility for Participation

Pharmacy Students / Graduates and Professionals working in pharma Industries.

Registration Details

Course fees : Rs. 1500/-

Registration Link :
<https://forms.gle/z56YL4i3E9HAMHpK8>

Last Date for Registration : 17/03/2023

Course Commencing From: 19/03/2023

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. Course Completion certificate will be provided by Gujarat Technological University, Ahmedabad

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



QUALITY MANAGEMENT

