



# ROFEL SHRI G.M. BILAKHIA COLLEGE OF PHARMACY

APPROVED BY PHARMACY COUNCIL OF INDIA (PCI) & AFFILIATED TO GUJARAT TECHNOLOGICAL UNIVERSITY, AHMEDABAD

**NAAC Accredited "B++" Grade Institution**

**Run by Rotary Foundation for Education and Learning (ROFEL) Trust**

ROFEL NAMDHA CAMPUS, Vapi-Namdha Road, P.B. No. 11, Vapi (West) - 396191, Dist.- Valsad (Gujarat)

Tel: 9727723722 | 42 | 62; Email: [info@rofelpharmacy.ac.in](mailto:info@rofelpharmacy.ac.in); Website: [www.rofelpharmacy.ac.in](http://www.rofelpharmacy.ac.in)

## SHORT TERM CERTIFICATE COURSE UNDER GTU-CCE ON PHARMACEUTICAL DRUG REGULATORY AFFAIRS

Centre for Continuing Education, GTU certified "Short Term Certificate Course on Pharmaceutical Drug Regulatory Affairs" was organized by ROFEL Shri G.M Bilakhia College of Pharmacy, Vapi. The first batch of this course was conducted from 10<sup>th</sup> September to 19<sup>th</sup> November, 2022.

Convenor- Dr. Arindam Paul (Principal)

Coordinators- Dr. Shuchi Desai (Associate Professor)

Dr. Hitesh Dalvadi (Professor)

### COURSE OBJECTIVE

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.

### DETAILS OF RESOURCE PERSONS

Name of Resource Person	Designation & work place	E.mail
Mr. Hiren Bhagat	Sr. Manager, Zydus Lifesciences Ltd., Ahmedabad, Gujarat	<a href="mailto:hirenbhagat2005@yahoo.co.in">hirenbhagat2005@yahoo.co.in</a>
Mr. Manoj Karwa	Head - CT and PV, Auriga Research Private Limited, Gurugram, Haryana	<a href="mailto:manojkarwa@aurigaresearch.com">manojkarwa@aurigaresearch.com</a>
Dr. Ronak Dedania	Head of the Department & Professor, Bhagwan Mahavir College of Pharmacy, Surat	<a href="mailto:dedaniaronak229@gmail.com">dedaniaronak229@gmail.com</a>
Mr. Tejash Shah	Director, Biopharm CMC Regulatory Affairs, GSK, London, UK	<a href="mailto:tejash.2.shah@gsk.com">tejash.2.shah@gsk.com</a>



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Ms. Iva Dhuliya	Manager, Isazi Pharma and Techno Consultancy Pvt. Ltd., Vadodara, Gujarat	<a href="mailto:iva.dhulia@isazi.biz">iva.dhulia@isazi.biz</a>
Mr. Umesh Dobariya	Associate Director, Isazi Pharma and Techno Consultancy Pvt. Ltd., Vadodara, Gujarat	<a href="mailto:umesh.dobariya@isazi.biz">umesh.dobariya@isazi.biz</a>
Mr. Devang Jani	Assistant Manager, Regulatory Affairs, Amneal Pharmaceuticals Ltd., Ahmedabad	<a href="mailto:janidev6@gmail.com">janidev6@gmail.com</a>
Mr. Vijay Satapara	Founder and CEO, Isazi Pharma and Techno Consultancy Pvt. Ltd. Vadodara, Gujarat	<a href="mailto:vijay.satapara@isazi.biz">vijay.satapara@isazi.biz</a>
Mr. Pragnesh Donga	In Charge – Regulatory Affairs, Zydus Lifesciences Limited / Zydus Therapeutics Inc., Ahmedabad	<a href="mailto:pragnesh.msu@gmail.com">pragnesh.msu@gmail.com</a>
Mr. Hansal Gandhi	Regulatory Affairs Executive, JAMP Pharma Group, Ahmedabad, Gujarat	<a href="mailto:hvgandhi21@gmail.com">hvgandhi21@gmail.com</a>

## SCHEDULE OF COURSE

Date	Name of Resource Person	Topic
10-09-22	Mr. Hiren Bhagat	Introduction, IND submission, format and content, General consideration of NDA, ANDA and SNDA, SUPAC, BACPAC, Post market survey
17-09-22	Mr. Manoj Karwa	Clinical trial phases, clinical trial protocols, HIPAA- new requirement to clinical study process
18-09-22	Dr. Ronak Dedania	Global submission of NDA, IND and ANDA, investigator brochure
24-09-22	Mr. Tejash Shah	Dossier, CMC requirements, Overview of CTD and eCTD <b>Practical-</b> Case study and demonstration of dossier preparation and filling.
25-09-22	Mr. Hansal Gandhi	Inspection and audits <b>Practical-</b> Case study of root cause analysis, CAPA and post-approval changes and documentation required for the same.

01-10-22	Mr. Manoj Karwa	Pharmacovigilance safety monitoring in clinical trial, regulation governing clinical trials
08-10-22	Ms. Iva Dhuliya	ICH Guidelines <b>Practical-</b> Case study of filling of CTD.
	Mr. Umesh Dobariya	Filling of CTD and eCTD
09-10-22	Mr. Devang Jani	Data integrity and importance of management of data integrity <b>Practical-</b> Demonstration and filling of DMF.
	Mr. Vijay Satpara	U.S Food & Drug Administration USDMF, Canada Therapeutic Product Directorate DMF <b>Practical-</b> Demonstration and filling of eCTD through the software.
15-10-22	Mr. Pragnesh Donga	UK-MHRA, ICH
19-11-22	External Exam 1) Dr. Ronak Dedania 2) Mr. Hansal Gandhi 3) Dr. Vinod Ramani	External Exam

## EVALUATION METHODOLOGY

Total 59 participants were enrolled in this course.

Sr. No.	Particular	Total Marks	Minimum Passing Marks
1.	Written google link MCQs Test	40	16
2.	Power point presentation of given topics	60	24
<b>Marks</b>		<b>100</b>	<b>50</b>

1. Students have to make power point presentation on assigned topics.

(On the basis of quality of presentation marks will be given.)

2. Written online google link MCQs Test

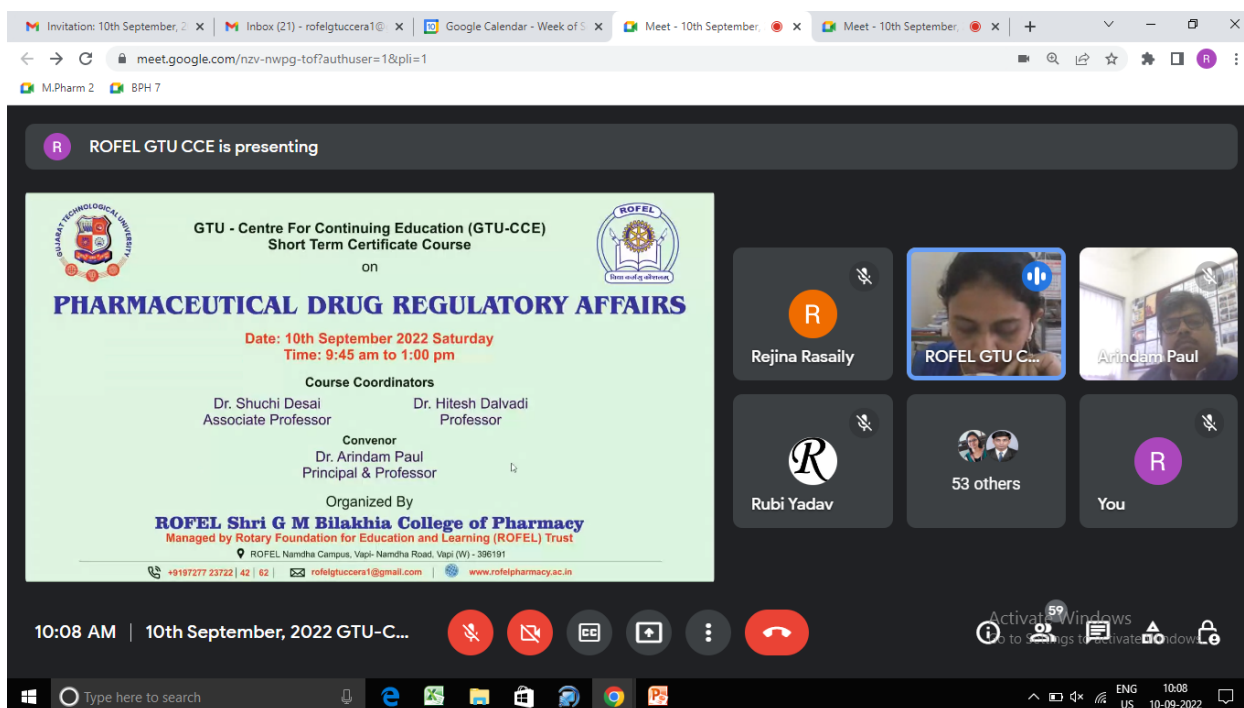
3. After Result of candidates (marks/grades) of Exam and Certificate will be issued by GTU.

All participants have passed examination with flying colours.

## COURSE OUTCOME

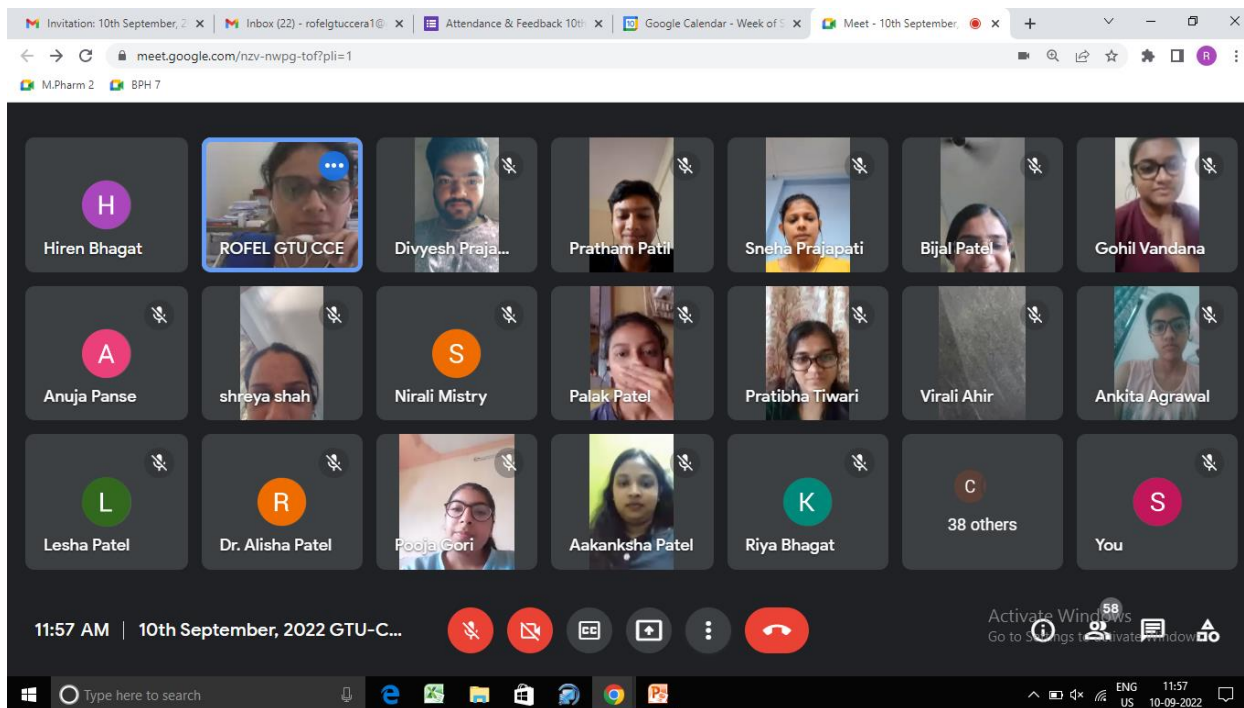

- Participants learnt the new drug approval process and its submission.
- Participants got the knowledge about guidelines to carry out pre-clinical and clinical studies required for new drug approval.
- Participants got the idea about the process of submission of global documents like dossier, CTD, eCTD,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

## FEW PHOTOGRAPHS OF THE SESSION

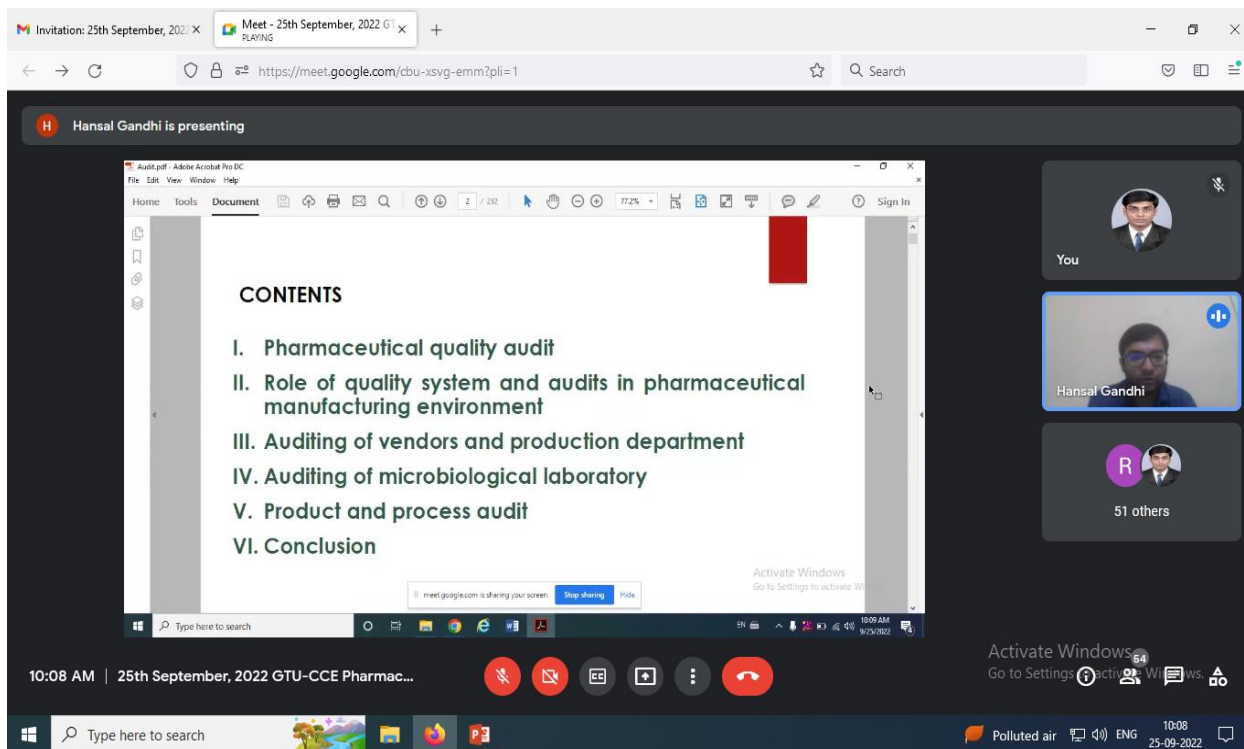


The screenshot shows a Google Meet interface during a session. The main content area displays a presentation slide titled "GTU - Centre For Continuing Education (GTU-CCE) Short Term Certificate Course on PHARMACEUTICAL DRUG REGULATORY AFFAIRS". The slide includes the date "10th September 2022 Saturday" and time "9:45 am to 1:00 pm". It lists course coordinators Dr. Shuchi Desai and Dr. Hitesh Dalvadi, and the convenor Dr. Arindam Paul. The course is organized by ROFEL Shri G M Bilakhia College of Pharmacy, managed by the Rotary Foundation for Education and Learning (ROFEL) Trust. The slide also provides contact information for the college.

On the right side of the screen, there are video thumbnails for participants: Rejina Rasaily, ROFEL GTU C..., Arindam Paul, Rubi Yadav, 53 others, and You. The bottom of the screen shows the Windows taskbar with the time 10:08 AM on 10th September, 2022.





Invitation: 25th September, 2022 | Meet - 25th September, 2022 GTU-CCE Pharmac... | PLAYING

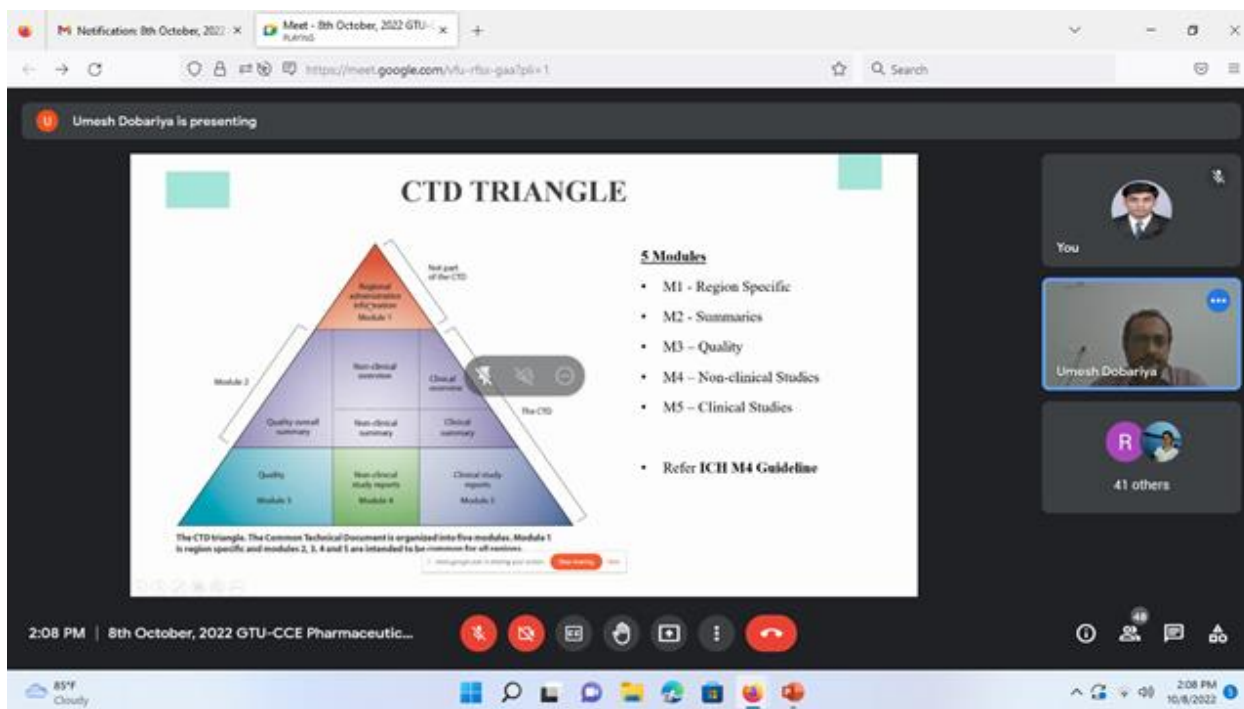
https://meet.google.com/cbu-xsvg-emm?pli=1

Hansal Gandhi is presenting

**CONTENTS**

- I. Pharmaceutical quality audit
- II. Role of quality system and audits in pharmaceutical manufacturing environment
- III. Auditing of vendors and production department
- IV. Auditing of microbiological laboratory
- V. Product and process audit
- VI. Conclusion

10:08 AM | 25th September, 2022 GTU-CCE Pharmac... | Activate Windows | Go to Settings to activate Windows.



Notifications: 8th October, 2022 | Meet - 8th October, 2022 GTU-CCE Pharmac... | PLAYING

https://meet.google.com/vfu-rts-gaa?pli=1

Umesh Dobariya is presenting

**CTD TRIANGLE**

Top part of the CTD: Regional administrative information Module 1

Non-clinical section: Quality control summary, Non-clinical summary, Clinical summary

Clinical section: Quality, Non-clinical study reports, Clinical study reports

**5 Modules**

- M1 - Region Specific
- M2 - Summaries
- M3 - Quality
- M4 - Non-clinical Studies
- M5 - Clinical Studies

Refer ICH M4 Guideline

The CTD Triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

2:08 PM | 8th October, 2022 GTU-CCE Pharmac... | 85°F Cloudy | 2:08 PM 10/8/2022

