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; Website: 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 10th September to 19th 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 | hirenbhagat2005@yahoo.co.in |
| Mr. Manoj Karwa | Head - CT and PV, Auriga Research Private Limited, Gurugram, Haryana | manojkarwa@aurigaresearch.com |
| Dr. Ronak Dedania | Head of the Department & Professor, Bhagwan Mahavir College of Pharmacy, Surat | dedaniaronak229@gmail.com |
| Mr. Tejash Shah | Director, Biopharm CMC Regulatory Affairs, GSK, London, UK | tejash.2.shah@gsk.com |

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

## 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<br>**Practical-** Case study and demonstration of dossier preparation and filling. |
| 25-09-22 | Mr. Hansal Gandhi | Inspection and audits<br>**Practical-** 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<br>**Practical-** 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<br>**Practical-** Demonstration and filling of DMF. |
| | Mr. Vijay Satpara | U.S Food & Drug Administration USDMF, Canada Therapeutic Product Directorate DMF<br>**Practical-** Demonstration and filling of eCTD through the software. |
| 15-10-22 | Mr. Pragnesh Donga | UK-MHRA,ICH |
| 19-11-22 | External Exam<br>1) Dr. Ronak Dedania<br>2) Mr. Hansal Gandhi<br>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 |
| **Marks** | | **100** | **50** |

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

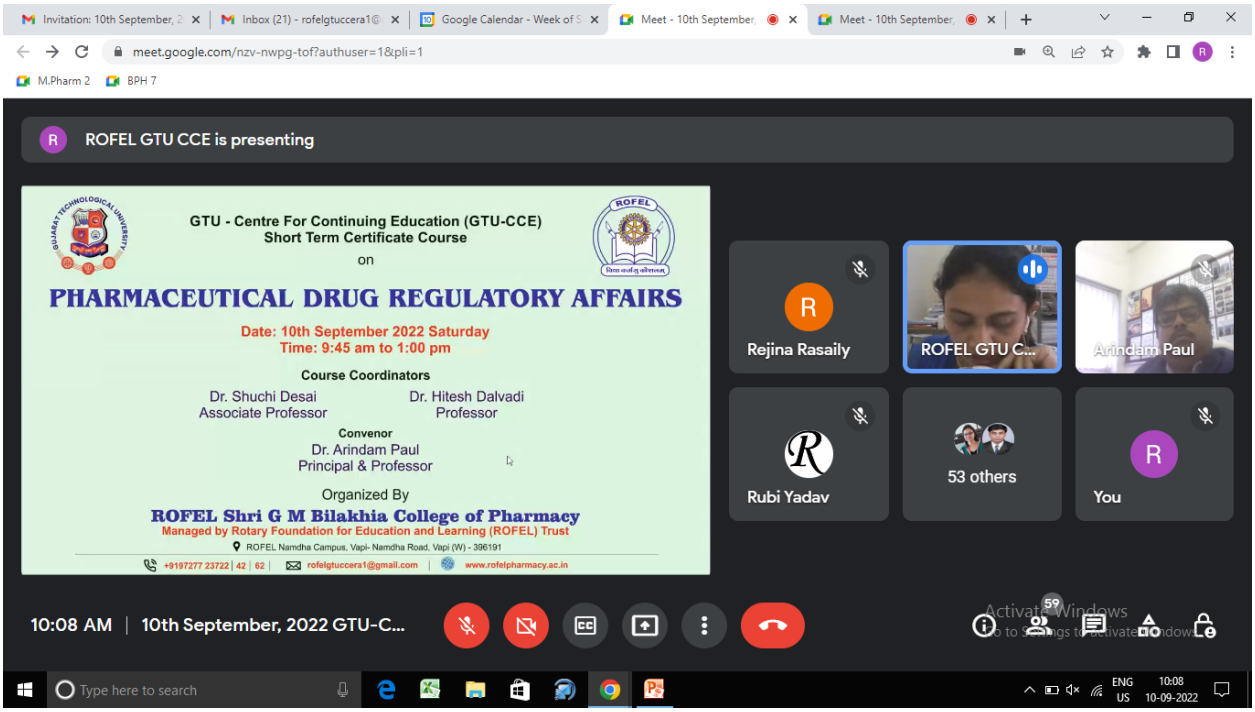
3. After Result of candidates (marks/grades) of Exam and Certificate will be issued by GTU.

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



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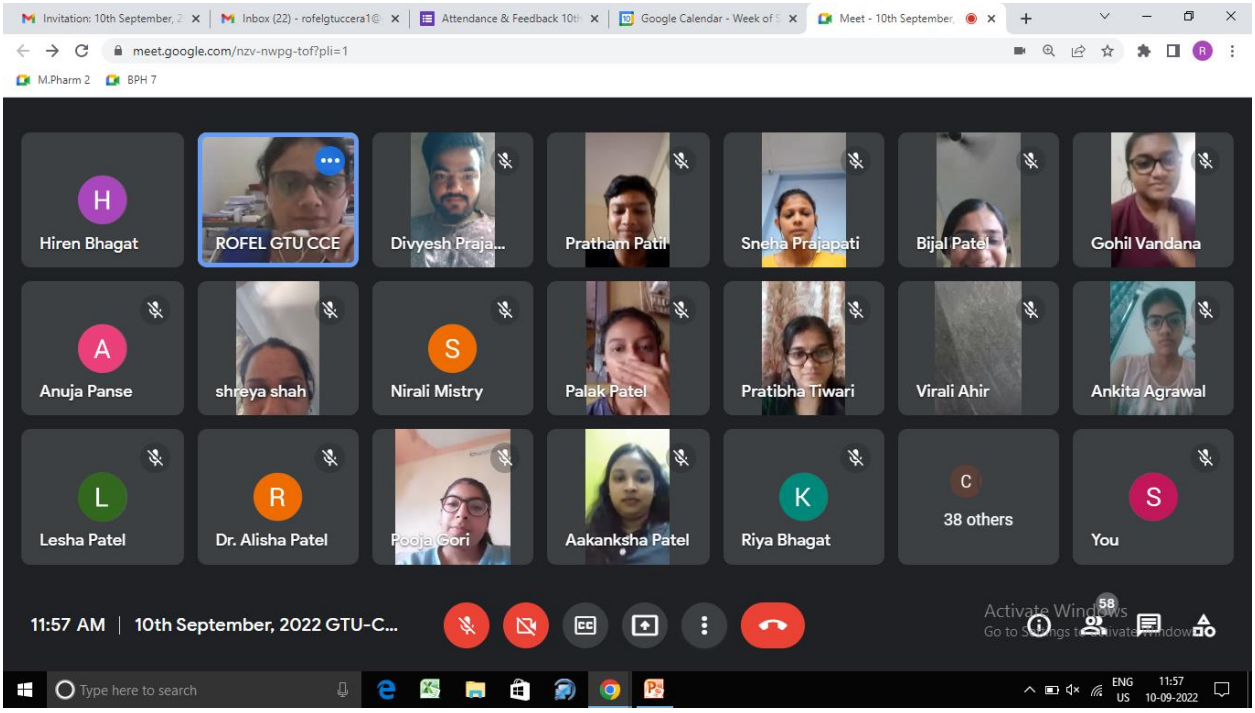


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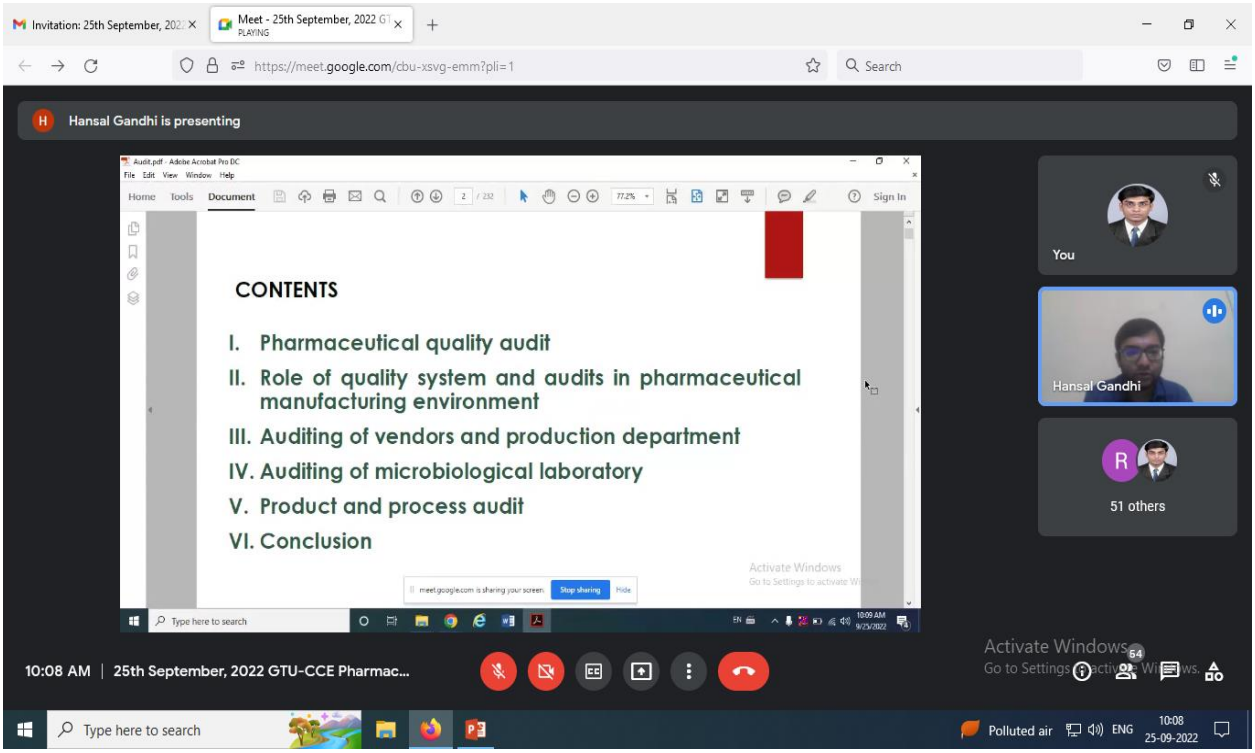


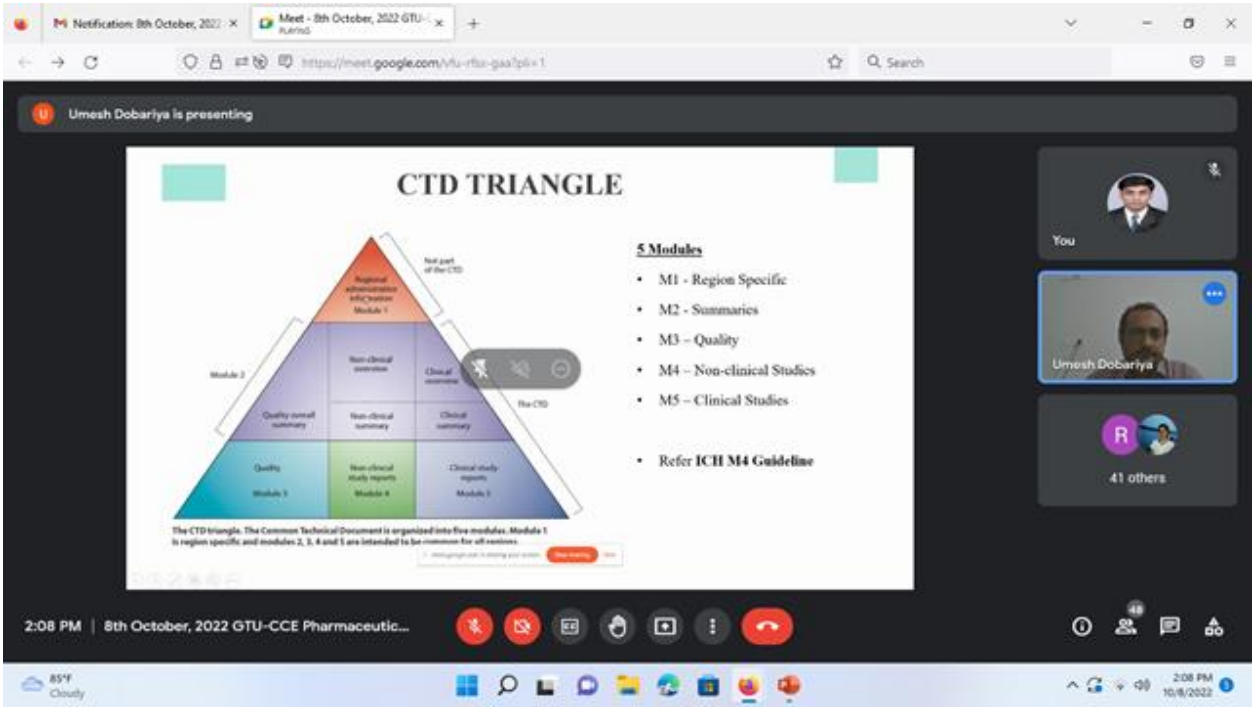

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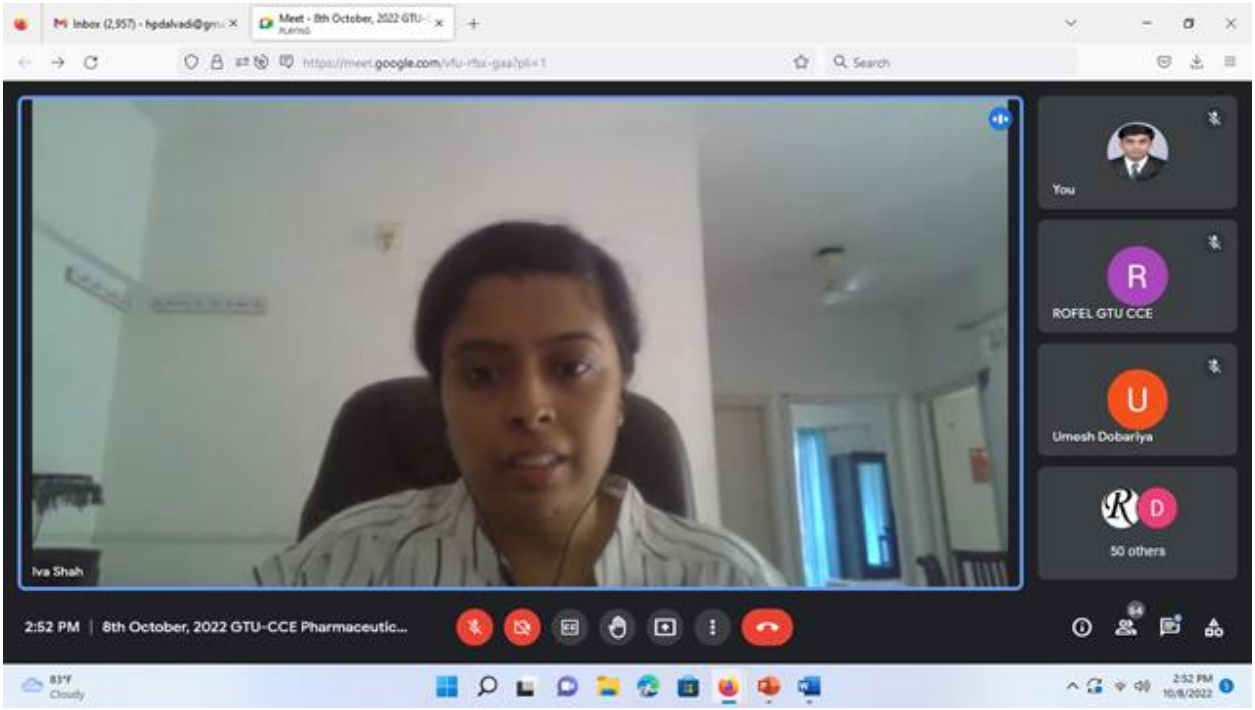


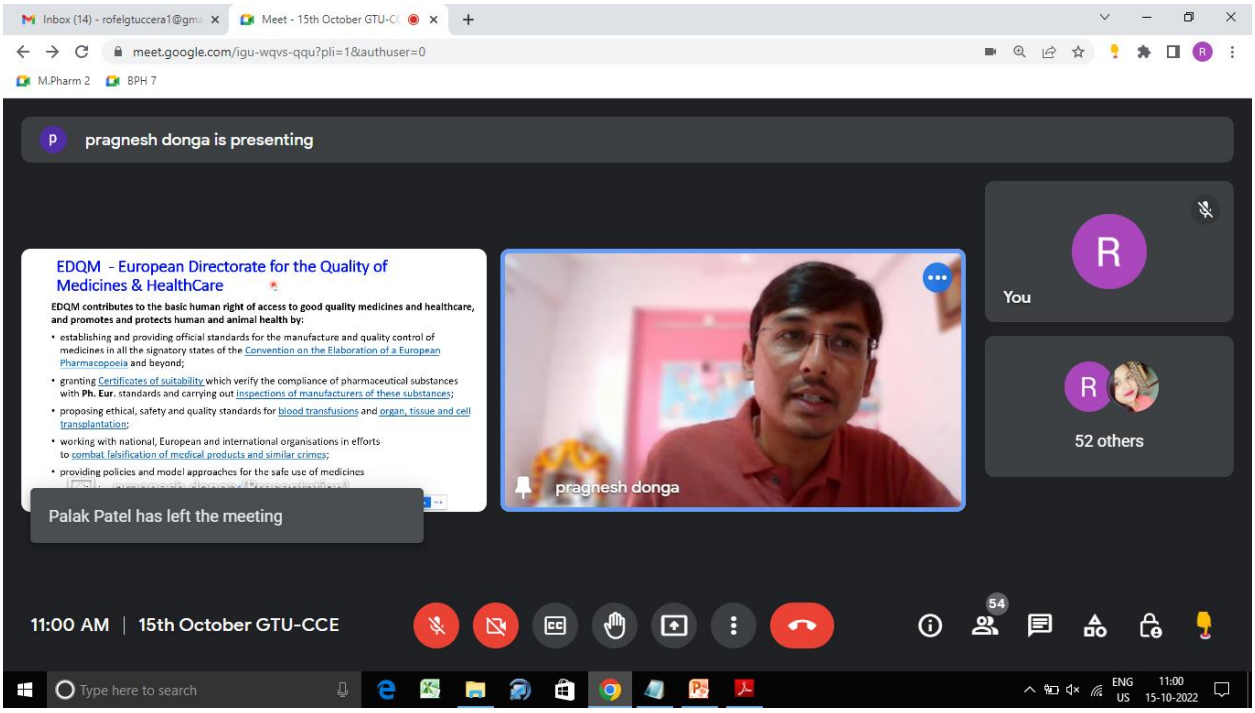

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