Report on

One day workshop on

Hands-on Training:

e-CTD Submission Process

28th March 2025

SCHOOL OF PHARMACY

GUJARAT TECHNOLOGICAL UNIVERSITY

Coordinator: Ms. Bhumika Maheriya

SUMMARY

Type of Event	Hands-on Training Session
Experts	1. Dr. Pranav Jogani, Professor of Practice, GTU-SP 2. Dr. Kashyap Thummar, Assistant Professor, GTU – SP 3. Ms. Bhumika Maheriya Assistant Professor, GTU - SP
Title of Session	Workshop on e-CTD Submission Process
Date of Event	28th March 2025
Venue	School of Pharmacy, Gujarat Technological University, Sector 26, Gandhinagar
Number of Participants	20
Coordinator	Ms. Bhumika Maheriya

1. Objective of the Workshop:

The primary objective of this one-day workshop was to provide participants with comprehensive understanding of the e-CTD format and dossier submission process by using e-CTD submission tools. This included an in-depth understanding of of regional and global regulatory requirements for eCTD submissions, preparation and compilation of regulatory submissions, training

of participants in using e-CTD submission tool and software and validation and review process of e-CTD dossier by regulatory authorities.

2. Workshop Sessions:

The workshop was structured into three insightful sessions, each delivered by subject matter experts.

Session 1: Evolution of CTD to eCTD; Speaker: Dr. Kashyap Thummar

- This session provided a historical overview of how regulatory submissions have evolved from paper-based CTDs to electronic formats. Dr. Thummar elaborated on the rationale behind the transition and its impact on regulatory efficiency and harmonization.

Session 2: Handling Regulatory Queries; Speaker: Dr. Pranav Jogani

- Dr. Jogani addressed the importance of timely and accurate responses to queries raised by regulatory authorities. He discussed common pitfalls and effective strategies to ensure continued compliance during the review process.

Session 3: Components of CTD and Global Requirements;

Speaker: Ms. Bhumika Maheriya

- Ms. Maheriya explained in detail the five modules of the CTD and their significance. She also compared submission requirements across various global regulatory agencies such as the US FDA, EMA, and CDSCO.

3. **Hands-On Training Session; Facilitator: Ms. Bhumika Maheriya**
    - A key highlight of the workshop was the hands-on training on eCTD submission. Participants were guided through the practical steps of compiling, validating, and publishing an eCTD dossier using specialized software tools. This session bridged the gap between theoretical understanding and real-world application.

4. **Learning Outcomes:**

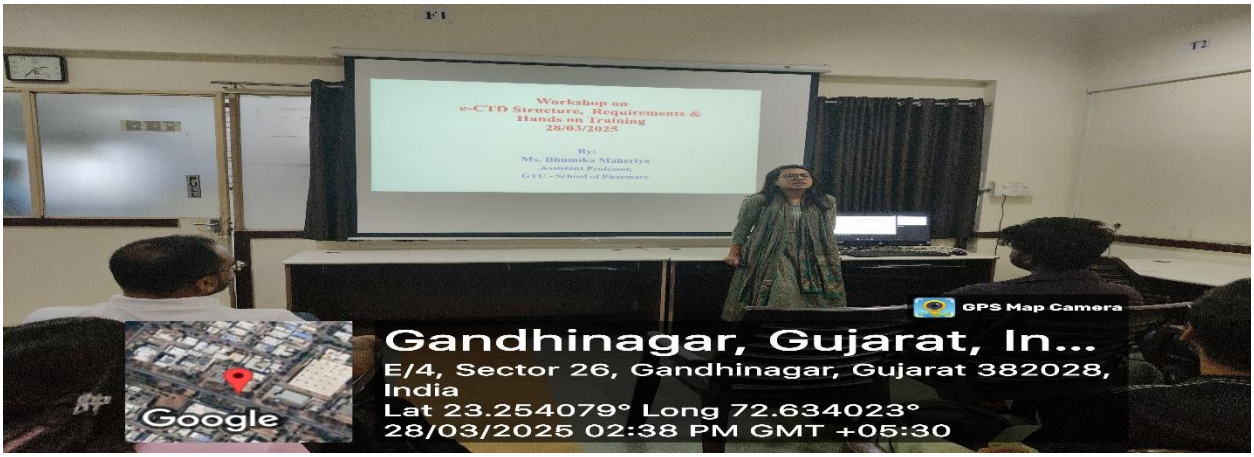
- Participants gained a thorough understanding of CTD and eCTD structure and its regulatory significance.
- Attendees acquired practical skills in compiling, publishing, and submitting eCTD dossiers.
- Participants became familiar with common regulatory queries and learned effective ways to address them.
- The workshop enhanced the ability to compare and align submissions as per different regulatory authority requirements.

Through hands-on practice, learners were empowered to apply theoretical knowledge to real-world regulatory processes.

5. **Participant Feedback**

Participants appreciated the balance between theoretical content and practical training. The interactive nature of the hands-on session was especially well-received. Many expressed interest in attending more advanced workshops in regulatory affairs and e-submissions.

Photographs of the Event:



Prepared by: Ms. Bhumika Maheriya; Assistant Professor, GTU – SP