



SUMMER SCHOOL 2026

Regulatory Affairs 4.0: eCTD, Artificial Intelligence & Global Submission Strategies

29th June to 3rd July 2026

Organised by

RegSphere Club, Department of Regulatory Affairs

Topics covered

- Global Submissions Framework
- eCTD & Emerging Trends
- Lifecycle management strategy
- Data exclusivity protection

Outcomes

- Practical skills in eCTD preparation & dossier review skills.
- Competence in regulatory strategy planning & evaluation
- Global regulatory guideline application
- Understanding AI & digital transformation in regulation

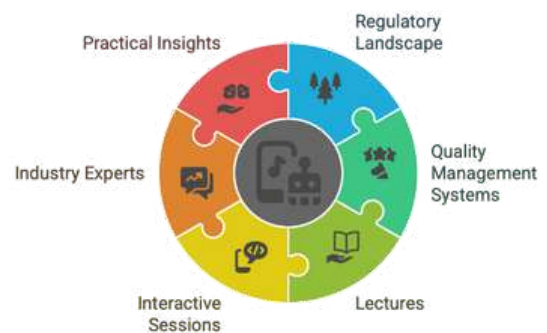
Organizers

Convener Dr. Jagannath Sahoo, Dean, SPPSPTM
Faculty Coordinator Dr. Khushwant Yadav, HOD RA
Student co-ordinators
Sidra Khan (8356884885)
Alfiya Mujawar (8652521766)

Objectives

- To provide a comprehensive understanding of global regulatory frameworks (USFDA, EMA, CDSCO) and submission pathways
- To train participants in eCTD structure, compilation, and lifecycle management for regulatory submissions
- To introduce the role of Artificial Intelligence and digital tools in regulatory decision-making and dossier optimization
- To bridge academia-industry gaps by focusing on practical regulatory workflows and real-world case studies

Key learnings



Venue: SPPSPTM, SVKM's NMIMS Deemed to be University, V.L. Mehta Road, Vile Parle (W), Mumbai-400056

For any queries, please contact:
Khushwant.yadav@nmims.edu

DAY-1

- Inauguration
- Emerging market requirements & submission challenges
- Regulatory strategy for ANDA submissions
- Q & A Session

DAY-2

- Regulatory aspects of software as medical device
- Post market safety monitoring of medical device
- Nutraceuticals: Safety, quality & labelling issues
- Q & A Session

DAY-3

- Smart regulation of biologics with AI integration
- Regulatory & Audit Deficiencies with Query Handling
- IPR: lab to commercialization
- Q & A Session

DAY-4

- eCTD Software Introduction
- Navigating eCTD: Challenges & system validation
- eCTD workshop
- Q & A Session

DAY-5

- Group activity: Mock submission/ Audit readiness
- Q & A Session, Quiz/Knowledge Challenge
- Group presentations
- Valedictory

Eligibility

- B.Pharm, M.Pharm Students
- PhD Research Scholars
- Faculty, Industry Professionals

Registration

Registration Fee:

Faculty / Students -Rs. 2000/-
Students (NMIMS) -Rs. 1500/-

Link for Registration:

<https://forms.gle/dmzSjWtCddoeDom17>

Limited 30 seats (On a first come, first serve basis)

Last Date to Register: 20th June 2026



Scan for registration and
payment