

MET'S Institute of Pharmacy

ACTIVITY REPORT

Name of Activity- **1st METRACon - National Level Conference on**

“Navigating the Fundamentals and Opportunities in Pharmaceutical Regulatory Affairs

Day and Date- 22th MArch 2025, Tuesday

	Offline	Online	Total	Course
Participants	251	87	338	B. Pharm, M. Pharm, Pharm D., Ph D Scholars, Academician, Industry Personnel

Details of the Program:

Conference was Inaugurated by **Ms Shruti Khardia**, Managing Director, Regtech India Solution as chief guest and accompanied by Dr. S. J. Kshirsagar, Principal, MET-IOP, Dr. S. S. Sonawane, Conveyer, HOD-RA, Ms. V.V. Gaidhani, Coordinator, Ms.M. V.Wadje, Coordinator. M. Shruti mam has also conducted a session on **‘Journey of Drug through Documentation’** in which she has covered Basics of RA, Industrial opportunities, RA agencies around the world, RA documentation.

Secon Session was conducted by **Dr. Parag Kulkarni**, Regulatory Affairs Lead - CMC, Medicom Healthcare, on topic of **‘Understanding of Module 3 for dossier preparation’**. Sir has focus on the Requirements of Chemistry, Manufacturing and Control data of Pharmaceutical Product and its documentation with practical examples.

Third Session was covered by **Dr. Anjali Apte**, Senior Manager, Regulatory affairs – CMC, Cencora PharmaLex on **‘Drug Development and Filing Applications for Investigational/New drugs and variation filings to FDA/EMA’**. Madam has introduce to concept of IND and NDA, impurity profiling and other requirement of filing. she also covered Case studies on Variation, and USFDA guidance in Comparison with EMA (EU)

Fourth session was conducted by **Mr. Amol Gotmare** Supply and Logistics Operations Manager, **PAREXEL International** on topic of **‘Clinical Trial Logistics and Supply’**. Sir has delivered Basics, Challenges, Overview of AI in Clinical Trial Logistics and Supply, its Benefits and discussed few Case study of clinical trial.

Fifth session was on **‘Hands on experience on Regulatory Submission Software- pharmaReady’** in which students has learn the function and application of e-CTD submission software in detail. Session was delivered by Team Navitas Life Sciences

Program was concluded after this and certificates were distributed to the students.

Programme outcomes attained

PO1	Pharmacy Knowledge	✓	PO7	Pharmaceutical Ethics	✓
PO2	Planning Abilities		PO8	Communication	
PO3	Problem Analysis	✓	PO9	The Pharmacist and society	✓
PO4	Modern Tool Usage	✓	PO10	Environment and Sustainability	

Dr. S. J. Kshirsagar
Principal

Dr. S. S. Sonawane
HOD

V. V. Gaidhani Mahima Wadje
Coordinator

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PO5	Leadership Skills		PO 11	Lifelong Learning	✓
PO6	Professional Identity	✓			

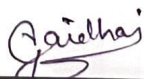
Objectives of the Activity	To guide the students on regulatory concepts and related topics'
Benefits of the activity	Students has learned the application of guidance and its documentation.
Social Media links	https://www.linkedin.com/posts/mets-iop-pharmaceutical-regulatory-affairs_4-renowned-industry-guest-speaker-5-sessions-activity-7310942826106695680-ccP?utm_source=share&utm_medium=member_desktop&rcm=ACoAACIZjZ4BlxmlUn79s6ZIPZUSzg5YolTxMIA

Photos of the event:




Dr. S. J. Kshirsagar
Principal


Dr. S. S. Sonawane
HOD


V. V. Gaidhani
Coordinator


Mahima Wadje
Coordinator