



Expert Talk on “Regulatory Considerations in Drug Discovery” by Ms. Payal Shah

Date : December 16, 2025

Time : 11:00 AM onwards

Venue : Shrimad Hall

Organized By : Maliba Pharmacy College in association with Internal Quality Assurance Cell (IQAC), Uka Tarsadia University

The expert talk was organized with the objective of providing students and faculty with in-depth insights into regulatory considerations involved in drug discovery, emphasizing global regulatory frameworks, strategic decision-making, and compliance requirements throughout the drug development lifecycle.

The session commenced with a welcome address by the organizing committee, followed by an introduction of the distinguished speaker, Ms. Payal Shah, working as Associate Director in Regulatory Affairs Strategy oncology department at ISPEN Biopharm, USA. Ms. Shah delivered a comprehensive lecture highlighting the role of regulatory affairs in drug discovery, starting from early preclinical stages to clinical development and eventual market authorization. She elaborated on key regulatory expectations of agencies such as the US FDA, EMA, and ICH, and discussed how regulatory strategies influence target selection, study design, and risk–benefit assessment.

Special emphasis was placed on:

- Regulatory pathways in oncology drug development
- Importance of early regulatory engagement

- Challenges in global regulatory submissions
- Integration of regulatory strategy with R&D processes

The session also included real-world examples from industry, which enhanced students' understanding of regulatory decision-making in pharmaceutical research. The expert talk witnessed active participation from M.Pharm students of Maliba Pharmacy College along with faculty members. The session proved highly beneficial for postgraduate students, particularly those interested in regulatory affairs, clinical research, and pharmaceutical industry careers. Students actively engaged in the interactive discussion and question-answer session, seeking clarification on regulatory career pathways, skill requirements, and industry expectations.

The expert talk was highly informative and aligned with the academic and professional development goals of Maliba Pharmacy College. The session successfully enriched the knowledge base of M.Pharm students and faculty, reinforcing the importance of regulatory science in modern drug discovery. The organizing committee expressed gratitude to Ms. Payal Shah for her valuable insights and to IQAC for their support in organizing the event.

NAAC Criteria : 5

Signature of Principal : Dr. Ashish D Mishra



