



Guidance to 8th Semester Students on Regulatory Affairs and Clinical Research

Date: 15/12/2025

Venue: DCVPCP

Speaker: Mrs. Payal Shah, Associate Director Regulatory Affairs at IPSEN Bioscience, USA

An expert session was organized for B. Pharm 8th semester students with the objective of providing early career guidance towards emerging professional pathways in **Regulatory Affairs** and **Clinical Research**. The session aimed to familiarize students with industry expectations, career scope, and skill requirements before graduation.

Objectives of the Session

- To introduce students to the fundamentals of Regulatory Affairs and Clinical Research.
- To create awareness about career opportunities in pharmaceutical, biotech, and CRO sectors.
- To guide students on academic preparation, certifications, and skill development required for these fields.
- To motivate students to plan their career path strategically during the final phase of their program.

The expert began with an overview of the pharmaceutical industry ecosystem, explaining how regulatory affairs and clinical research play a critical role in ensuring drug safety, efficacy, and compliance.

The session provided comprehensive guidance on Regulatory Affairs and Clinical Research as promising career pathways for Pharm D students. The expert explained the role of regulatory professionals in drug approval, regulatory documentation, compliance, and lifecycle management, along with an overview of major regulatory bodies such as US FDA. Key responsibilities discussed included dossier preparation, regulatory submissions, and post-approval activities, highlighting essential skills such as regulatory writing, thorough understanding of guidelines, accuracy, and attention to detail.

In the Clinical Research segment, the expert introduced clinical trials and their phases (Phase I–IV) and elaborated on various career roles available for graduates, including Clinical Research Coordinator (CRC), Clinical Research Associate (CRA), and Pharmacovigilance Associate.

The session further focused on career guidance and skill development, stressing the importance of internships, project work, hands-on exposure, and relevant certifications in GCP, Regulatory Affairs, and Clinical Research. Students were encouraged to strengthen communication, documentation, and

basic data interpretation skills, and to stay updated with evolving regulatory guidelines and industry trends. The session was highly interactive, with active student participation and queries related to job roles, salary expectations, higher education, and global opportunities, and the practical insights shared by the expert helped students gain clarity about real-world expectations and challenges in these professional domains.

