

JSS Academy of Higher Education & Research, Mysuru
JSS College of Pharmacy,
Sri Shivarathreeshwara Nagara, Mysuru

Date: 10th August, 2019

Report on Guest Lecture

Speaker: Mr Krishna Chaitanya, Asst. Manager – Regulatory Affair, Dr. Reddy's Labs, Hyderabad

Title: Basics of Dossier compilation – CTD Format.

Date: 9th August 2019

Venue: RA Seminar Hall, JSSCP, Mysuru

Students of program: 1st M. Pharm students of Pharmaceutical Regulatory Affairs, Pharmaceutical Quality Assurance, Pharmaceutics and Industrial Pharmacy

Dr Venkatesh M.P Assistant Professor, Department of Pharmaceutics introduced about the speaker to the students and delivered opening remarks. Mr Krishna Chaitanya delivered a talk on the Basics of Dossier compilation – CTD Format. Mr. Chaitanya started the session by giving information about the responsibilities of regulatory Affairs personnel in drug registration, audits and other activities in the industry. He discussed about the objective of regulatory submission, General regulatory scenario, global market segregation, stability conditions in different climatic zones, and certain mandatory regulatory requirements to be full filled by the pharmaceutical industry for filing for the market authorization approval in different countries.

He coded few examples, and highlighted the importance of various markets like regulated, emerging, non-regulated and also informed about the registration procedure to be followed in the emerging market countries. He explained about CTD and its organizational setup and in particular about module 3 which deals with quality aspect of the Pharmaceutical product.

He shared his personnel experience as a student and also about his working experience in industry. He explained about the drug substance and drug product sections of quality module, the open and closed part of DMF submitted to regulatory authorities and the challenges faced by the pharma company during the process of approval.

He concluded the session by updating the students about the scope of their profession, clarifying our doubts and by describing challenges and problems in Pharmaceutical Sciences.

