

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

Date: 11th November, 2019

Report on Guest Lecture

Speaker: Dr. A Ramkishan, Deputy Drugs Controller (CDSCO), East Zone, Kolkata

Title: Regulatory framework: Recent initiatives by Govt. of India.

Date: 11th November, 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. M P Venkatesh, Assistant Professor, Department of Pharmaceutics, introduced the guest to the students and his accolades and success as a part of CDSCO officer. Dr. Ramkishan delivered a talk on the said topic and introduced about Indian regulatory framework and its perspectives. He provided the information about various departments of pharmacy, their role; the requirement of innovation in the current generation was emphasized. It was made as an interactive session by involving the students.

He presented the vision and mission of the CDSCO, proceeding with the drugs definition according to D and C Act and evolution of the Indian Drug Legislation; organization of the Indian Drug Regulatory System and different departments falling under them; various roles played by the CDSCO in the perspective of Drugs and its role in various organizations.

Dr. Ramkishan explained about the possible opportunities from the manufactures and countries for export and import of drugs; countries holding maximum shares and their level of growth regarding exports from year to year. He also explained India's contribution in drug exports with the other countries, objectives of pharmaceutical Policy 2017, new provisions regarding orphan drugs; an overview of Indian vaccine industry, its exports and newly released policy.

He also provided notable information on the NRA Assessment, its objectives and WHO developed assessment tool also called as Benchmarking Tool'. Levels of Maturity based on the functionality of NRA namely 1-5 levels. The WHO Assessors were listed and places they belong to were given. He also shared his experience as being a CDSCO officer and the level of integrity that is expected from the regulators viz., USFDA, WHO etc.

He updated us with the current steps taken by the CDSCO for the development of Pharmacovigilance in India; importance of Patient Safety was stressed as the main part in the Global level.

Recent advancements in Indian Regulations were brought to the notice like e-Governance program in India, clinical trials, new regulation in India for medical devices, upgradation of schedule M and Development of intelligence cell at the CDSCO Headquarters.

Amendments made to the D & C Act and Rules 1945 i.e., the establishment of the Public Relation Office and Salient features regarding the New Drugs Clinical Trial were provided.

A vast amount of information was provided by Dr. Ramkishan. The various opportunities for the graduating pharmacists in the profession were detailed; the questions raised by the students were promptly answered. Dr. M.P. Venkatesh proposed the vote of thanks and profusely thanked Dr. A. Ramkishan for his elaborate and meaningful insight on the current scenario of regulatory in India.

