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

Date: 31st August 2024

REPORT on Webinar

"Indian Drug Regulations and Regulatory Compliance"

Speakers:

1. Dr. Anandakirouchene, M Pharm, PhD, MBA(HRM), Controlling Cum Licensing Authority, Department of Drugs Control, Puducherry.
2. Mr. Lalit Kumar Goel, Deputy State Drugs, Controller FDA, Haryana.

Faculty of Program:

1. Dr. K Bangarurajan, Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.
2. Dr. M P Venkatesh, Associate Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.

Students of Program:

1st & 2nd year M. Pharm Pharmaceutical Regulatory Affairs and PhD Scholars of JSS College of Pharmacy, Mysuru.

Date: 31st August 2024

Discussion

1. Dr. T M Pramod Kumar, Professor & Principal, JSS College of Pharmacy, welcomed the participants and introduced them to the webinar.
2. Dr. K Bangarurajan, Professor, Regulatory Affairs Group, Department of Pharmaceutics delivered opening remarks.
3. Dr. M P Venkatesh, Associate Professor, Regulatory Affairs Group, Department of Pharmaceutics gave an introduction of the speakers to the students.

Speaker 1: Dr. Anandakirouchene

Dr. Anandakirouchene was the first speaker of the webinar, and he delivered a talk on topic "An Overview on Regulatory Compliance in Pharmaceutical Industry". He gave a brief

explanation about the importance of Regulatory compliance to a company which is adherence to laws, regulations, guidelines, and specifications relevant to its business processes. It is a fundamental aspect of any industry, ensuring that organizations operate within legal and ethical boundaries, maintain industry standards, and manage risks effectively.

The key aspects that the speaker highlighted in the secession was Drug Development and Approvals, Good Manufacturing Practice (GMP), Environmental compliance, Quality Assurance and Control, Ethical and Legal Compliance. GMP and Environmental Compliance are two of the main things to be complied with, where GMP outlines that the product manufactured are up to the quality standards and the Environment safety guidelines focussed about the necessary actions to be taken during clearances from bodies such as the Pollution Control Boards of the respective states.

Taking about the startups and Subsidy from the government he mentioned about Atal Incubation Centres (AICs) that are key initiative under the Atal Innovation Mission (AIM) of the Government of India, aimed at fostering innovation and entrepreneurship across the country. It was launched in 2016, and the mission is part of the larger vision to create a robust startup ecosystem in India.

He concluded the presentation by summarizing Regulatory compliance in the pharma industry which is essential for ensuring the safety and quality of medications. Adhering to stringent guidelines set by bodies helps protect public health, foster trust and maintain high industry standards. In an ever-evolving regulatory landscape, pharmaceutical companies must remain Vigilant and proactive, continuously updating their compliance strategies to align with current laws and best practices. In the questionnaire, speaker explained the differences in licencing of drugs in different State Licencing Authority and in the Union Territories.

Speaker 2: Mr. Lalit Kumar Goel

Dr. Bangarurajan introduced Mr. Lalit Kumar Goel, Deputy State Drugs Controller, FDA Haryana to the participants. He delivered an insightful presentation on the Medical Devices Rules (MDR), 2017. He detailed the definitions and classifications of medical devices under the MDR, highlighting the four classes based on risk levels, which guide the regulatory controls required. He also emphasized the importance of biocompatibility, adherence to standards such as BIS, ISO, and IEC, and the unique labelling requirements for medical devices. Mr. Goel compared the regulatory landscape before and after the introduction of MDR, 2017, noting the significant improvements in regulatory stringency and quality control. He provided an overview of the fee structures for different device classes and the role of Quality Management Systems outlined the 5th Schedule of MDR, 2017.

The speaker detailed the role of central medical testing laboratories designated as appellate laboratories under MDR, 2017. These laboratories, such as the National Institute of Biologicals (Noida) and the Central Drug Testing Laboratory (Chennai), play a crucial role in testing and certifying medical devices to ensure they meet the necessary safety and performance standards.

He also discussed the conditions for the registration and sale of medical devices in India. He emphasized the mandatory requirement for an import license for medical devices, which ensures that only compliant products enter the Indian market. He also highlighted the regulatory conditions that must be met for the sale of medical devices, ensuring that they are safe and effective for use.

He concluded with an oversight on the critical role of regulatory compliance in ensuring the safety and efficacy of medical devices.

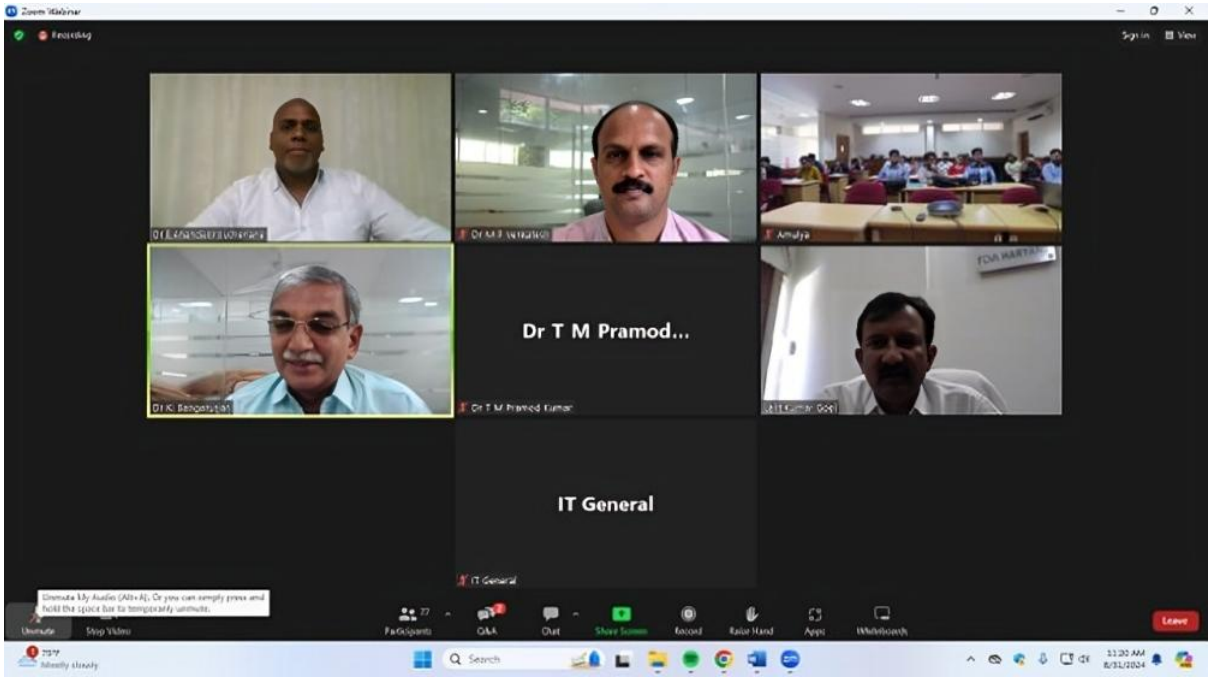

Figure 1: Introducing the speakers, Dr. Anandakirouchene and Mr. Lalit Kumar Goel to the gathering.

Figure 2: First session by Dr. Anandakirouchene. Topic: "An Overview on Regulatory Compliance in Pharmaceutical Industry".

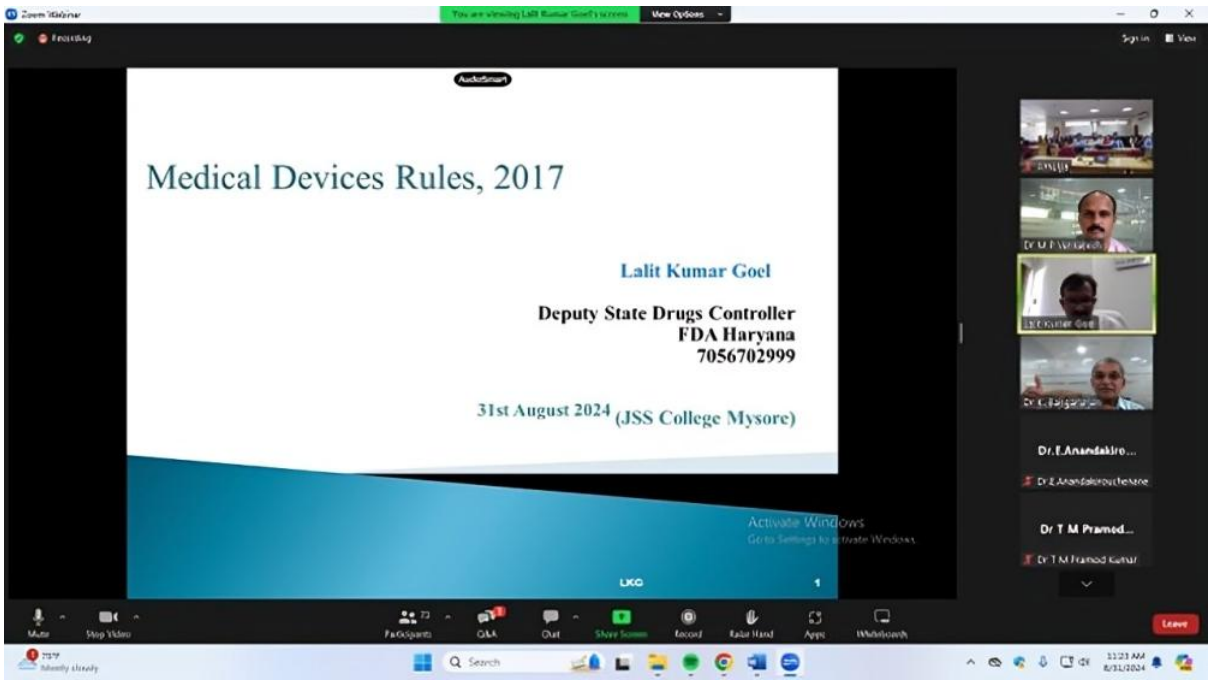

Figure 3: Second Session by Lalit Kumar Goel. Topic: Medical Devices Rules, 2017"