# JSS Academy of Higher Education & Research

## JSS College of Pharmacy

Sri Shivarathreeshwara Nagara, Bannimantap, Mysuru, Karnataka, India - 570015

**Date**: March 22nd 2024

## REPORT ON GUEST LECTURE

**TOPIC: REGULATORY EXPECTATIONS FOR QUALITY COMPLIANCE - PROPOSED REVISION OF SCHEDULE M**

**Speaker**: Mr. Jayant Kumar

Deputy Drugs Controller (India)

CDSCO, West Zone, Mumbai

**Faculty of Program**

Dr. K Bangarurajan, Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru.

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

**Students of Program:**

1st and 2nd M. Pharm, Pharmaceutical Regulatory Affairs, Dept. of Pharmaceutics, Ph.D. scholars (Pharmaceutical Regulatory Affairs), JSS College of Pharmacy, Mysuru.

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Dr. M P Venkatesh, Associate Professor, Department of Pharmaceutics, Pharmaceutical Regulatory Affairs Group, JSS College of Pharmacy, Mysuru gave a brief introduction about the speaker to the participants.

Mr Jayant Kumar, delivered a talk on the topic “Regulatory Expectations for Quality Compliance - Proposed Revision of Schedule M”. He briefed about the importance of GMP in Pharmaceutical Manufacturing process.

He explained about the background of GMP including about the role of drugs in Public Healthcare system, Import, Manufacture, Sale and Distribution of Drugs, Cosmetics and Medical Devices & Drug Regulations to ensure Safety, Efficacy and Quality etc. His talk continued with objectives and insights to manufacturers about Revised GMP and to aware about new provisions in the revised Schedule M, disseminate new provisions to all stakeholders well in advance and to make manufacturers ready for implementation etc.

The speaker shared the insights on history of Good Manufacturing Practices (GMP) that dates back to 1961, with initial requirements focusing on equipment and premises. Subsequent amendments in 1986 and 2001,

based on WHO guidelines, aimed to enhance the quality standards in pharmaceutical manufacturing. However, over time, concerns and challenges emerged, including inconsistent manufacturing practices, irregular batches, and the need for robust formulation development and stability studies. These challenges highlighted the necessity for a comprehensive revision of GMP standards to address evolving industry needs and global quality benchmarks.

By Recognizing the importance of GMP, for both ensuring consistent product quality and maintaining consumer trust, he said that pharmaceutical industry has embraced its principles, further on he added GMP serves as a vital framework to prevent mix-ups, contamination, and errors, ensuring product quality throughout its shelf life and safeguarding patient safety. Moreover, adherence to GMP standards is crucial for regulatory compliance and fostering consumer confidence in the pharmaceutical sector.

As he moved forward to explain the need for revision of GMP standards, culminating the introduction of the revised Schedule M, stems from the dynamic nature of the industry. Advances in technology, changing regulatory requirements, and emerging quality standards necessitate periodic updates to GMP guidelines. The revised Schedule M aims to align with global standards, facilitate innovation, and enhance quality awareness across the pharmaceutical sector. He further explained that by integrating the latest advancements and best practices, the revised Schedule M seeks to ensure India's competitiveness in the global pharmaceutical market.

The critical key changes in the revised Schedule M enclose a strengthened focus on quality systems and risk management, expanded sanitation and validation requirements, and enhanced compliance reporting and product recall protocols were explained. These changes are designed to elevate manufacturing standards, improve product quality, and mitigate risks associated with pharmaceutical manufacturing processes. Ultimately, the revised Schedule M underscores India's commitment to upholding global quality standards and fostering a culture of continuous improvement within the pharmaceutical industry.

He concluded that the revised Schedule M represents a significant milestone in India's journey towards achieving and maintaining excellence in pharmaceutical manufacturing. By embracing these revisions and prioritizing adherence to GMP standards, manufacturers can ensure sustained growth, competitiveness, and adherence to global quality benchmarks.

The session was interactive, the speakers attended the queries raised by the students and faculty.

**Vote of thanks:**

Dr. K Bangarurajan extended heartfelt thanks to Mr Jayant Kumar for sharing their expertise in topic. His insights have inspired and enriched us profoundly.

***Fig 1:*** *Dr. M P Venkatesh giving a brief introduction of Speaker to attendees*


***Fig 2:*** *Mr. Jayant Kumar explaining about Proposed Revision of Schedule M*


***Fig 3:*** *Attendees of Program*


***Fig 4:*** *Dr. K Bangarurajan giving insight about Proposed Revision of Schedule M & Vote of thanks*