

## **JSS ACADEMY OF HIGHER EDUCATION & RESEARCH**

### **JSS COLLEGE OF PHARMACY, MYSURU**

#### **GUEST LECTURE REPORT**

**Title:** Case study on cGMP

**Date:** August 2<sup>nd</sup> 2019

**Guest lecture by:** Mr. A.G Raghu

Director, Strategy and Quality Control

Arkgen Pharma private Ltd, Bangalore.

Consultant, Santhana Gopala Consultants

Mr. A.G Raghu Guest delivered a guest lecture on 2<sup>nd</sup> August. The program started at 12:00 PM. During the first session he presented some of the video clips informative regarding the case study of the good manufacturing practice in pharmaceutical industry for maintaining the specified quality of a product. The key components required are knowledge and skill of the competent person, team work and personal responsibility.



In the second session, importance of documentation in Pharmaceutical industry was taught. The following contents: documentation of QMS, records, procedure, policy, data, documentation and records.



Good documentation practice [GDP] depends on ‘ALCOA’

- A - Attributable
- L – legible or long lasting
- C – complete
- O – original
- A – accurate

At last he concluded the seminar by giving lecture on Data integrity, Data life cycle and breach of Data integrity.

This seminar was helpful for students regarding documentation, cGMP and Data integrity. This seminar was attended by 30 students belonging to departments of Pharmaceutical Quality Assurance and Regulatory Affairs. The lecture was concluded at 4:00 PM.