JSS Academy of Higher Education And Research
JSS College of Pharmacy, Mysuru
Guest Lecture on "GxP Reviews – Lifecycle of GxP"

Report

Date: January 16, 2023

Topic: Lecture on "GxP Reviews – Lifecycle of GxP"

Speaker:

Name: Mr Cuddapah Sandeep

Company: Accenture Technology Centre, Bengaluru, India

Designation: Technical support Associate Manager

Guest Lecture was organized by the department of Pharmaceutics, Pharmaceutical Quality Assurance group, JSS College of Pharmacy, Mysuru on 16.01.2023 from 4:00 pm to 5:00 pm on topic "GxP Reviews – Lifecycle of GxP" by Mr Cuddapah Sandeep, Accenture Technology Centre, Technical support Associate Manager for First year M Pharm students in Seminar Hall.

He began his session by giving brief introduction about GxP. GxP compliance guidelines were established in the U.S. by the Food and Drug Administration (FDA). Additionally, he narrated students regarding "5 Ps" of GxP and its application in Pharmaceuticals.

Mr Cuddapah explained the basics of Good Automated Manufacturing Practice, Founded in 1991. International Society for Pharmaceutical Engineering (ISPE) sets the guidelines for

manufacturers and the current Version is GAMP 5. And he also stressed the importance of Computer system validation (CSV) following GAMP guidelines require users and suppliers to work together so that responsibilities regarding the validation process are understood.

Further, he also briefed about 21 CFR Part 11 which defines the US FDA regulations that set forth the criteria applies to electronic records and electronic signatures that persons create, modifies, maintain, archive, retrieve, or transmit under any records or signature requirement set forth in the Federal Food, Drug, and Cosmetic Act. Annex 11 is part of the European GMP Guidelines and specifies the terms of reference for computerized systems software used by organizations in the pharmaceutical industry. After delivering his lecture he encouraged students to keep themselves updated with current pharmaceutical affairs and enhance their knowledge through different online courses. All the students found this program very educative and informative.

The event ended with a question-answer session followed by a vote of thanks by Dr Hemanth Kumar S, Co-ordinator of the Pharmaceutical Quality Assurance Department.