

**Report on
On
One Day Workshop on Clinical Research and Regulatory Requirements**

Date: 9th March 2019

Venue: Seminar Hall, JSS CoP, Ooty

Program Organized By:
Dept. of Pharmacy Practice
JSS College of Pharmacy
Ooty

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One Day Workshop on Clinical Research and Regulatory requirements was organized by the Dept. of Pharmacy Practice on 9th March 2019. About 95 participants participated in the program. This program is aimed to develop the skills and understanding of the pharmacy students in clinical research and its regulatory requirements in India.

During this one day program on clinical research covered various topics in clinical research. It includes the overview of drug development process which covered overall drug development process in detail and where clinical research fits in overall scheme of drug development process. It also covered various phases of clinical research. Further, why Clinical Research in India covered the need to conduct clinical research in India as well as it gave overview of facilities available for clinical research in India. Further, it also covered the history of clinical research and how various guidelines on clinical research evolved over the period of last few centuries.

ICH – GCP_was covered in detail which included responsibilities of responsibilities of various stakeholders in the process of clinical research. Essential Documents such as protocol, informed consent process and Investigator brochure along with many other required documents in the process of conducting clinical research were covered using role play and involving participants. Data Management and Case Report Forms_were covered in detail including differences between paper case report form and electronic case report form as well as overall data management process. Pharmacovigilance process which has to be followed in not only clinical research but also in overall drug development and post marketing was covered. Finally session was concluded with providing overview of career options in clinical research and gave insight on process followed by organizations in hiring of the potential candidates for employment in clinical research companies.



