

JSS COLLEGE OF PHARMACY OOTY



pharmaREADY

Workshop Report

TWO DAYS WORKSHOP ON eCTD SOFTWARE AND HANDS ON TRAINING.

September 29th & 30th 2022

ORGANISED BY: Pharmaceutical regulatory affairs

Department of pharmaceutics

Co ordinated by: NAVITAS LIFE SCIENCES

This workshop was a hands-on learning experience for the students of the regulatory affairs and pharmaceutics department. There was a demo session followed by a practical session which included filling of the eCTD document

Day 1

The day one started with the inauguration by our teachers Dr. R. SureshKumar Dr.GNK.Ganesh, Dr K Gowthamarajan, Dr Sathyanarayana Reddy and Mr Vivek Reddy.

Dr K Gowthamarajan and Dr GNK Ganesh briefed about the workshop and its take aways.

Mr.Mohanraj Purushotaman started the session one by giving an introduction to eCTD ,fundamentals of eCTD and other methods for submitting the dossier. He also gave a brief outline on global submission format. In session 2 he gave us a complete demo on pharmaREADY eCTDsoftware, he explained us how to fill each sections of eCTD ,importance of granularity of folders, placing of modules from 1-5, importance of study tagging files in module 4&5.

Day 2

In day two session one we had hands on training in the pharmaREADY software and the presenter clarified all our doubts regarding the eCTD software.

We continued to work with the software in session two and finally we had a feedback session of the two days' workshop.

The workshop ended with good feedback from the participants and interaction with the, Dr K Gowthamarajan, Dr. R. SureshKumar Dr.GNK.Ganesh ,Dr Sathyanarayana Reddy and Mr Vivek Reddy .

It gave us an idea as to how technical documents are filled in the industry. The minor details and intricate technicality of the filling process were taught by our eminent speakers. It was a great learning experience and we can implement this knowledge in our future if need be. Looking forward to attending similar sessions in the future to further strengthen our practical skills.

Students Interaction



Training for live projects



Appreciation for best performers

