A Report on the Two-day workshop on eCTD software

A two-day workshop and hands-on training of eCTD software were conducted on 4th and 5th of October 2018 by Mr. Mohanraj Purushothaman and Mr. Barghav Reddy from Navitas, Chennai. A total of 28 students from Pharmaceutics, Regulatory Affairs and Industrial Pharmacy Ist year M. pharmacy attended the workshop. Dr. GNK Ganesh, co-ordinated the entire event.

Day 1

The sessions commenced at 9.00 AM, Dr. Ganesh introduced the trainers from Navitas and cordially invited them to conduct the training. He also explained the genesis of the eCTD software. Mr. Mohanraj gave a short introduction about Navitas and Pharmaready eCTD software. Then he explained about an overview of eCTD, an overview of pharmaREADY Application and demonstration of PharmaREADY eCTD modules and its features.

The training session was dispersed for lunch at 1.00 PM and the workshop resumed at 2.00 PM.

During the afternoon session, Mr. Barghav demonstrated the creation of eCTD application for FDA Agency, including metadata creation (regulatory identifiers, eCTD master data), application creation, sequence creation, user assigning, module addition, uploading of submission documents, working on eCTD specification and PDF properties, compile, validate, hyperlink-bookmarking, recompile and validate, revision sequence creation and Agency specifications (USFDA, EU). The session ended with questions and answers and clarification of doubts at 5.00 PM

Day 2

The sessions started at 9.00 AM with a short recap of day 1. The students were divided into 9 groups sswith one computer system each. Accounts were created for each group with a separate username and password. Each group was given a task to create an eCTD application by creating metadata and sequence, the addition of modules, uploading submission documents, hyperlinking, bookmarking compiling and validating.

Mr. Mohanraj assessed each group's work in the afternoon session and provided valuable feedback.

At the close of the second day's session, Ms. Geetha S of Regulatory Affairs said vote of thanks. The session came to an end by 5.00 PM.

Some glimpses of the eCTD workshop.