

JSS Academy of Higher Education & Research

JSS College of Pharmacy, Mysuru

REPORT

eCTD Hands-on-Training

26th and 27th September, 2019

Venue: Regulatory Affairs Lab, JSS College of Pharmacy, Mysuru

Participants: Faculty of Pharmaceutics and Students of

- 1st and 2nd year M Pharm in Pharmaceutical Regulatory Affairs,
- 1st M Pharm in Pharmaceutical Quality Assurance,
- 1st M Pharm in Pharmaceutics,
- 1st M Pharm in Industrial Pharmacy

NAVITAS Life Science's TakeSolutions is an enterprise, comprised of dedicated life science professionals operating in North America, Europe, Asia and South America with a rich legacy of experience in life sciences they have worked with 9 of the top 10 pharmaceutical companies and have a popular software version Called PharmaReady which have been used by the pharma companies to submit electronic Common Technical Document (eCTD) to various Regulatory Authorities.

Mr. Vijaykumar Srinivasan (Associate Program Manager) Bengaluru, Mr. Bharanitharan Boominathan (Senior Implementation and Support Engineer) and Mr. Ajay (Senior Implementation and Support Engineer) were the trainers for the 2 days training programme on eCTD.

Dr. M.P Venkatesh Assistant professor, Department of Pharmaceutics introduced about the speaker and objective of the training to the students. He gave a brief overview on how eCTD submissions happen and briefed about NAVITAS and their eCTD submission software. He also explained about the Common Technical Document and its importance in regulatory documentation submission in the Pharmaceutical industry.



Dr. M.P Venkatesh explaining about eCTD training and NAVITAS PharmaReady software

DAY 1: 26th September, 2019

Mr. Vijaykumar Srinivasan started the morning session by giving the overview of PharmaReady eCTD software. He briefed about the need of regulatory submission, their structure and difference between the various submission formats (comparison between Paper, NeeS, eCTD formats and the ACTD formats.)



Mr. Vijaykumar Srinivasan briefed about the eCTD submissions

He discussed on the fundamentals of eCTD & its benefits, Global perspective into the market requirements; also deliberated on various Tools and Technologies for eCTD submission and explained about the components of RIMS. A demonstration on the PharmaReady software was made.

The afternoon session was interactive, where Mr. Vijaykumar Srinivasan asked the students to volunteer to create an eCTD submission. He then demonstrated different steps and procedures to be followed to carry out the EU and Health Canada submissions. The session concluded by clearing the issues related to submission; emphasis was made to create submission for EU, Health Canada and US the next day in a group of two.

DAY 2: 27th September, 2019

The session started by detailing the steps to login to the PharmaReady website (IP address, login ID and password on the sandbox). Later, the students had a practical and interactive session, where Mr. Bharanitharan Boominathan assisted students in the filing an US submission. The students started creating submission on the instructions of the trainers; the day continued by filing the submission for EU and Health Canada.

65 students of Dept. of Pharmaceutics took the benefit of the eCTD submission across various Regulatory bodies i.e. US, EU and Health Canada. The day was interacting and the students gained vast experience in filling submissions for regulatory bodies. The day ended with a questionnaire session and feedback was collected regarding the two-day session.

The NAVITAS team also expressed their support to attend the queries/ issues related to eCTD submissions for the complete learning. They also shared the stepwise procedure about eCTD submissions.

Dr. Venkatesh M.P, Assistant professor, Department of Pharmaceutics concluded the session by felicitating the NAVITAS team and thanked them for their valuable time and extending their support for better learning experience to the students.

We thank JSS Academy of Higher Education and Research and JSS College of Pharmacy, Mysuru for providing an opportunity for the students to get trained on eCTD submissions, an important component in Pharmaceutical Regulatory Affairs.

