

**REPORT ON**  
**“Dossier Compilation and Submission using PharmaReady (eCTD) Software”**  
**5<sup>th</sup> and 6<sup>th</sup> December, 2017**

**Trainers**

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Navitas Life Sciences, Chennai

Venue: Regulatory Affairs Lab, JSSCP, Mysuru

**Introduction**

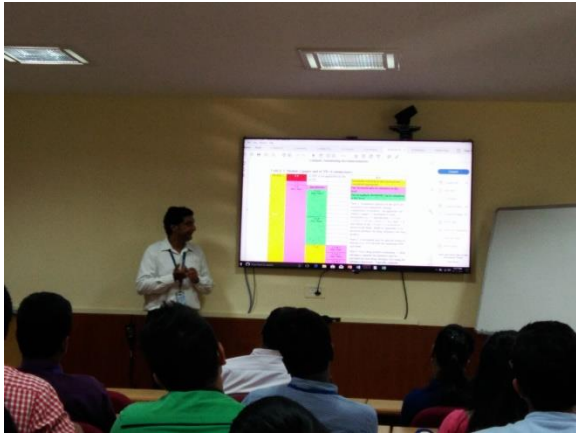
Department of Pharmaceutics, JSS College of Pharmacy, Mysuru organised a two day training session on “Dossier Compilation and Submission using PharmaReady (eCTD) Software” on 5<sup>th</sup> and 6<sup>th</sup> December, 2017 coordinated by Regulatory Affairs Group at RA Seminar Hall. The objective of the session is to impart the knowledge about the PharmaReady eCTD (Electronic Common Technical Document) software. The students pursuing M.Pharm, PG Diploma and Ph.D. in Pharmaceutical Regulatory Affairs were attended.

Navitas Life Sciences’ PharmaReady is a fully integrated, regulatory compliant, web-based suite comprised of Document Management, Training Records Management, Structured Product Labelling, and eCTD Publishing Solutions. Pharmaready simplifies the complex process of creating, viewing, and managing submissions – electronic, Nees or paper submission.

**Day 1 (5<sup>th</sup> Dec 2017)**

The session was started at 10:00AM which was hosted by Dr.M.P Venkatesh where the trainers were welcomed and students were addressed about importance of usage of software for regulatory submissions, followed by the introduction and brief information about the global scenarios and requirements for the submissions for regulatory authority of different countries like USA, Canada, European Union and its member states, South Africa and GCC etc by the trainers. The session lasted till 1:00 PM.

During Post lunch session, the trainer demonstrated the various steps included in the operation of the software for the different submissions which was followed by voluntary participation of the students where they were asked to perform the same. The session concluded at 5:30PM.



## Day 2 (5<sup>th</sup> Dec 2017)

The day started with a session about the Life Cycle Management and EU submission at 9:00AM and concluded at 10:00AM. A round of questionnaire was conducted up to 11:00 AM. Hands on training for the students started at 11:45AM in the Digital Library of the Medical College. The students were paired up and were asked to operate the software as shown by the trainer previously. The trainers guided the students while they were performing the given task. The session went on till 1:00PM.

Post Lunch session included the continuation of the ongoing / pending assignment. The Hands on session ended up by 4:00PM. This was followed by a discussion on the practice and implementation of the software. The discussion ended on a positive note where the trainers clarified the doubts of the students regarding the software operation which was followed by the photo session. The session ended up by a Vote of Thanks by Dr M P Venkatesh, Asst. Professor, Pharmaceutical Regulatory Affairs.

