

## **Report on**

### ***AICTE Sponsored***

Two Days National Seminar on

### **“Impact of Recent Policy Changes on Pharmaceutical Industries”**

01<sup>st</sup>& 02<sup>nd</sup>March, 2019

### ***Co-Sponsored by***

Special Interest Group on Policy Research – JSSAHER, Mysuru

IPA-Nilgiris Local Branch

#### **Pre – conference workshop:**

A pre-conference workshop was organized on 28<sup>th</sup> February, 2019 to provide hands-on training in eCTD Software.

**Speaker:**MohanrajPurushothaman from NAVITAS LIFESCIENCES

**Software used:**pharmaREADYeCTD Software.

**No. of participants:** 22

#### **Objectives of workshop were:**

- Understand the need for Regulatory Submissions
- Differentiate between the different submission formats
- Go over the Fundamentals of eCTD
- Quick look into the Market Requirements
- Exposure to the various Tools and Technologies

#### **Conduct of training:**

- The workshop started with a small presentation about the overview of e-CTD submission.
- Followed by there was a complete demo on the e-CTD submission to US regulatory agency, FDA.
- In the afternoon session, the students were asked to try using e-CTD software for submission to US regulatory agency, FDA.

- ❑ The training started from the login into the Pharmaready website, regulatory identifiers, e-CTD dashboard filling, creating application, sequence property filling, assigning of users for managing, approving and publishing of the dossier, addition of modules, generation of checksum, addition of new documents, updating of old documents, deletion of documents, compilation, preview, validation, use of custom template, synchronization.
- ❑ The workshop was very much useful for the students which helped them in having knowledge in e-CTD submission to US regulatory agency.



National Seminar:

The seminar was organized on 01<sup>st</sup> and 02<sup>nd</sup> of March 2019.

No. of External delegates: 224

No. of Internal delegates: 105

The delegates were from various places like Karnataka, Tamil Nadu, Kerala, Andhra Pradesh, Telangana, Maharashtra.

The Seminar was organized to invite experts and key officials from Indian regulatory division and to enroll as many researchers, academicians, students, policy makers etc. As possible, effort is to spread the knowledge on the regulatory updates in the pharmaceutical sciences.

Invited Guests:

- **Dr. B Suresh**, Vice Chancellor, JSSAHER and President of PCI.
- **Dr. C G Betsurmth**, Executive Secretary, JSSMVP, Mysuru.
- **Dr. K. Bangarurajan**, Joint Drugs Controller, CDSCO, New Delhi
- **Dr. SmitaKulkarni**, Scientist F & Dy. Director, National AIDS Research Institute (NARI) - ICMR, Pune
- **Dr. HiriyanRavikumar**, Joint Director of Health Services, The Nilgiris
- **Dr. M Easwaramurthy**, Principal, Government Arts College, Ooty
- **Dr. Srinivas Reddy**, Managing Director, TAN TEA, The Nilgiris
- **Prof. K. Chinnaswami**, President, IACP, Chennai

Invited Speakers:

DAY 01 (01/03/2019)

- **Dr. K Bangarurajan**, Joints Drug Controller of India, CDSCO has given a talk on **“Recent changes in Drug regulation in India”**.
- **Dr.SumatiRandeo**, SME & Adviser, Indian Pharmacopeial Commission, MHFW India has given talk on **“Medical Device Regulatory & Conformity Model”**.
- **Dr. Ramesh Jagadeesan**, Senior. Director, Regulatory & Analytical, Recipharm, Bangalore has given a talk on the topic **“Dietary supplements and nutraceuticals regulation consideration”**
- **Dr. Ramanathan L**, AGM, Apex India Pvt. Ltd., Chennai has given a talk on the topic **“Regulation Pathway for EU approval and BREXIT”**.

Day 02 (02/03/2019)

- **Dr.SumatiRandeo**, SME & Adviser, Indian Pharmacopeial Commission, MHFW India has given talk on **“Clinical Investigations Regulatory Requirements for Medical Devices”**.
- **Dr. Manavalan**, Asst. Drug Controller, CDSCO has given a talk on **“Implication of GSR 133 and regulation of FDC on Pharmaceutical Industry”**.
- **Dr. Ramanathan L**, AGM, Apex India Pvt. Ltd., Chennai has given a talk on the topic **“Regulation Pathway for Innovative products in India”**.
- **Dr. J P Prasad**, Scientist Grade I, NIB, New Delhi, has given a talk on the topic **“Development and regulation of Biologicals and biosimilars, current status and future challenges”**.

#### **e-Poster Presentation:**

No. of Participants: 70.

Awardees: (CASH PRIZE)

First Prize: (INR 8000/-)

- a) Ms.Sandhya C, JSSCollege of Pharmacy, Ooty.
- b) Mr.Abhishek S Keralli, JSSCollege of Pharmacy, Ooty.

Second Prize: (INR 4000/-)

- a) B Sumalatha Devi, JSS College of Pharmacy, Ooty.
- b) Kamireddy Karuna, JSS College of Pharmacy, Mysuru.

Third Prize: (INR 2000/-)

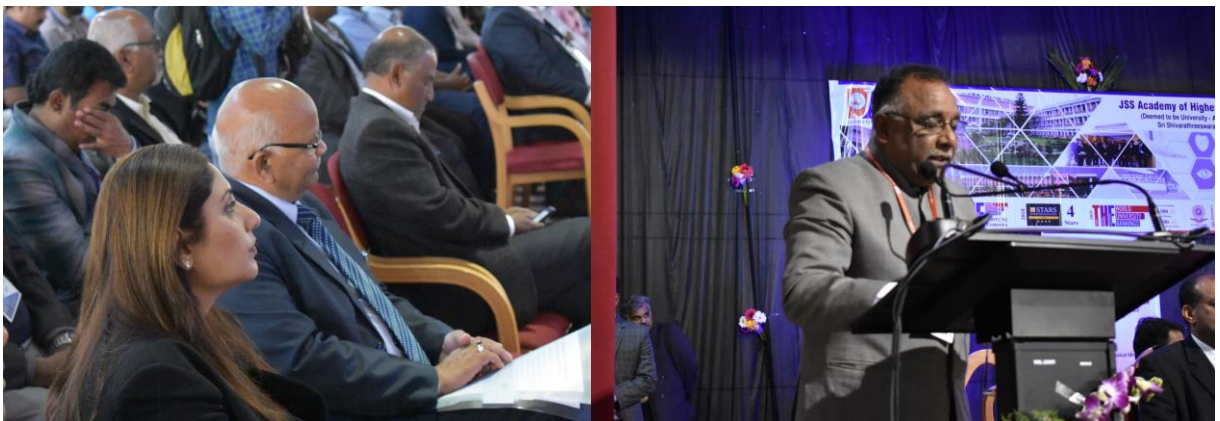
- a) Venugopal N, JSS College of Pharmacy, Ooty.
- b) Vivekanandan S, JSS College of Pharmacy, Ooty.



**Guests for Inaugural Function.**

**Lamp Lightening Ceremony by the guest**

**Welcome Address by Dr. S P Dhanabal, Principal, JSSCP, Ooty**





**Key Note Address by Dr. B Suresh, Vice Chancellor, JSSAHER and President, PCI**

**Presidential dress by Dr. C G Betsurmath, Executive Secretary, JSSMVP, Mysuru**





**Scientific Session by Dr. K Bangarurajan, Joints Drug Controller, CDSCO**

**Scientific Session by Dr. J P Prasad, Scientist Grade I, NIB, New Delhi**







**Scientific Session by Dr. SumatiRandeo, SME & Adviser, Indian Pharmacopoeial Commission, MHFW India.**

**Scientific Session by Dr. Ramanathan L, AGM, Apex India Pvt. Ltd., Chennai**





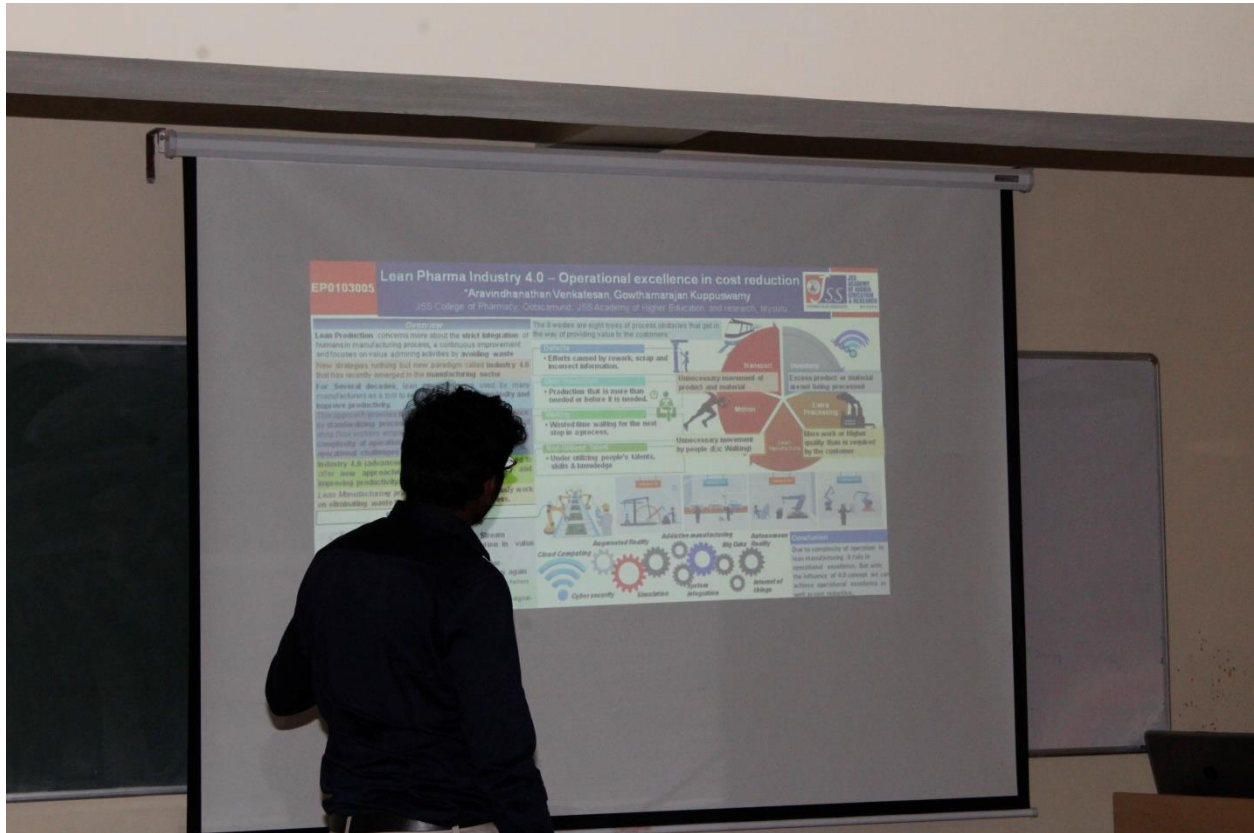
**Scientific Session by Dr. Ramesh Jagadeesan, Senior. Director, Regulatory & Analytical, Recipharm, Bangalore**

**Scientific Session by Dr. Manavalan, Assistant. Drug Controller, CDSCO**



## E-Poster Presentation Programme





## Valedictory Function





E-Poster Awardees

