

**JSS Academy of Higher Education and Research
JSS College of Pharmacy
Sri Shivarathreeshwara Nagar, Mysuru-570015**

**Pharmacy Council of India, New Delhi sponsored
FDP on “Teaching Regulatory Affairs for M.Pharm Programme”
9th – 14th April, 2018**

REPORT

The Faculty Development Programme (FDP) started with the inauguration. Dr. B. Manjunatha, Registrar, JSS Academy of Higher Education and Research was the Chief Guest, Dr. Krathish Bopanna, President & Chief Executive Officer, Semler Research Centre, Bengaluru and Mr. Umesh Baikunje, Founder - Baikunje consultancy, Bengaluru were the Guests of Honor; Dr. T.M. Pramod Kumar, Principal, JSSCPM presided the occasion and Dr. D.V.Gowda, convenor of FDP were present in the inaugural program.

Dr. T.M. Pramod Kumar, Principal, JSSCPM welcomed the gathering and briefed about the objectives of the FDP. The chief guest and guests of honour highlighted the importance of Faculty development program and the need in the current scenario. During the inaugural session, “Pharma Regulatory Compendium”, a compilation of achievements of the Regulatory Affairs Group at JSSCP, Mysuru was unveiled by the guests. The guests appreciated the journey of Regulatory Affairs Program in the institution. Dr. D.V. Gowda proposed the vote of thanks.



**Dignitaries inaugurating the event by
Lighting the lamp**



**Release of “Pharm. Regulatory Compendium”
by Dr. B. Manjunatha, Registrar, JSS AHER**

Seventeen (17) participants from different Pharmacy institutions across South India participated in the FDP. The objective of FDP was to appraise the participants about

- Basic elements of regulatory sciences
- Documentation and clinical practices for regulatory approvals
- Regulatory requirements for US, EU, UK, Australia and ROW countries
- Provide Hands-on-training on eCTD compilation and submission

The distinguished speakers and the topics delivered during the FDP are:

Sl. No.	Date	Name and affiliation of speaker	Title of topic
1.	9 th April, 2018	Dr. Kratish Bopanna CEO & President, Semler Research Pvt Ltd, Bengaluru	Clinical Drug Development Process
2.		Dr. Umesh Baikunje Founder, Baikunje Consultants, Bengaluru	Dossier- Formats & Compilation
3.		Dr. A.G. Raghu Santhana Gopala Consultants, Mysuru	Documentation in Pharmaceutical Industry
4.	10 th April, 2018	Mr. Siddharth Sahai ADC, CDSCO, New Delhi	Concept of Generics
5.		Dr. M.P. Venkatesh Asst. Professor, JSS College of Pharmacy, Mysuru	Drug Product Performance – <i>In Vitro</i>
6.		Mr. Yogesh Shelar ADC, CDSCO, New Delhi	Drug Product Performance – <i>In Vivo</i>
7.		Mr. Anabarasu Chinnasamy Sr. Manager-RA, Mylan Labs Ltd, Bengaluru	Generic Drug Product Development
8.	11 th April, 2018	Mr. Bobby George VP & Head – RA, Reliance Life Sciences, Mumbai	Clinical Trials-Basics, Investigator’s Brochure & IMPD Clinical Trial Protocol
9.		Dr. Harrison Michael Zaphery Regulatory Solution Manager, Aris Global Software Pvt Ltd, Bengaluru	Scale up and post approval changes (SUPAC
10.		Dr. Balamuralidhara V Asst. Professor, JSS College of Pharmacy, Mysuru	Regulations for combination products and medical devices
11.	12 th April, 2018	Mr. Singaravelan Radhakrishnan RAC, GM – RA & Compliance, Apotex India, Bengaluru	Regulatory requirements for Generics in MHRA & EU
12.		Mr. Ramam B S Panchangam Manager – RA & TPM, Pharmaleaf India Pvt Ltd, Bengaluru	Regulatory requirements in TGA and ROW countries
13.		Dr. Sriram Akundi V Senior VP & Global Head – Quality & National Regulatory, Biocon Limited, Bengaluru	US-FDA Basics & application Types
14.		Mr. Prabhakaran N Senior Team Leader – RA, Strides Shasun Ltd, Bengaluru	Approval Process of NDA & ANDA
15.	13 th & 14 th April, 2018	Dr. Uma Nandan Misra Dean, Pharma Training Institute, Bengaluru	International Council of Harmonisation (ICH) guidelines
16.		Mr. Ashok J Implementation & Support Engineer, Navitas LLC, Chennai	Global perspective & Overview of eCTD
17.		Mr. Bharanitharan B Senior Implementation & Support Engineer, Navitas LLC, Chennai	Hands-on-training sessions

The first four days of the program was based on the deliberations from the experts in the focussed area; the sessions were interactive providing simple and actual examples to make the concept clear and easy to understand; Question and Answer round at the end of each session gave clarity on the related learning outcomes.

The FDP program was able to cover most of the important topics listed in the Regulatory Affairs subject of M.Pharm – Pharmaceuticals course. All the topics were well described, discussed, deliberated and appreciated by the participants. They expressed their satisfaction at the end of each session which was coupled with feedback reports.

The participants visited JSS Hospital at Mysuru, an 1800 bedded super-speciality hospital to understand the clinical pharmacy related activities including the conduct of clinical trials and its documentation. The participants were apprised of the good practices in the hospital. It was well accepted and appreciated.

The last two days focussed on providing Hands-on-training on eCTD software (PharmReady®) by Navitas LLC, Chennai. A session about the history of electronic submissions was provided to understand the regulatory submissions; fundamentals of eCTD and differences between various types of submissions were provided which paved for the easy understanding of requirements.

The FDP concluded with the formal valedictory; the occasion was graced by Dr. T.M. Pramod Kumar, Principal and Dr. P.K. Kulkarni, Vice Principal of the college. A vote of thanks was proposed by Dr. M.P Venkatesh followed by a feedback from the participants about the programme. The Principal and Vice Principal also addressed the participants and gave away certificates, copies of all the presentations and the study material related to the subject.

Dr. Balamuralidhara and Dr. M.P. Venkatesh, Asst. Professors of Pharmaceutics department were the co-convenors of the program who took the lead from concept to conceptualization of this FDP program.

The faculty development programme was altogether a learning process for everyone. It was a learning experience and it created an opportunity to interaction with experts from various industries. It was a week of knowledge which the participants and the students experienced and cherished.

We thank Pharmacy Council of India, New Delhi for generously supporting these activities of the institution. We thank JSS Academy of Higher Education and Research for encouraging the planning and conducting Faculty Development Program.



Dr. B. Manjunatha, Registrar, JSS AHER (sitting; 5th from left) with Dr. T.M. Pramod Kumar, Principal, JSSCPM (sitting; 4th from left) with speakers and participants of FDP