

## **Report on one-day Workshop "Current Practices in Drug regulatory Affairs"**

Proceedings of the one-day Workshop Sponsored by the JSS University-Mysore and the Indian Pharmaceutical Association-Nilgiris Branch entitled, "Current Practices in Drug regulatory Affairs" held on February 21, 2015.

About 50 external participants from Tamil Nadu, Kerala, Karnataka and Andhrapradesh states had registered. About 4 resource persons had conducted the Workshop, as follows:

Session (1) was conducted by **Dr.Amit Kumar Devagan of Nestor Pharmaceuticals, Goa** in which he appraised about the Bioequivalence Requirements for the USA Pharma markets. He had presented 5 Case Studies, each illustrating how Nestor Pharmaceuticals, Goa had solved the real-life problems related to Bioequivalence.

Session (2) was conducted by **Dr.Shajjad Hussein of the Regulatory Affairs Department of Manipal University** in which he appraised about the procedures involved in the filing of an Abbreviated New Drug Application (ANDA) for the USA Food and Drug Agency (FDA).

Session (3) was conducted by **Mr.Prabhakaran of Strides Arco Limited, Bangalore**, in which he appraised about the Chemistry, Manufacturing and Control (CMC) requirements and Labeling (Approved Pharmacological Indications) requirements when Indian Drugs have to be exported to the USA, Japan and the European Union (EU) markets.

Last Session (4) was conducted by **Dr.Satish Kumar Menon of Agappe Diagnostics Ltd.- Ernakulam**, in which he taught the participants - How to Register a Pharmaceutical Product under the Indian Drugs Controller General's Office?

**For a practitioner of Regulatory Affairs and for an entrepreneur the Workshop would have been extremely useful due to the following reasons:**

- 1) They could get their doubts cleared.
- 2) They could get website links to the global Regulatory Authorities and
- 3) They could get confidence as everything - Regulatory was explained very clearly.

Finally Prof.S.Sankar and Prof.V.Senthil of JSS College of Pharmacy, Ooty wish to convey to 1) JSS University- Mysore the highly invaluable Sponsorship of Rs 30,000/- which was everything they needed to make this workshop a success.

2) Indian Pharmaceutical Association-Nilgiris Branch their acknowledgement for Stationary material Sponsorship for all the participants.