Write up on Faculty development program
on
"Teaching Regulatory Affairs for M.Pharm Programme"

Dr.D.Prasanthi, Associate Professor, Pharmaceutics department, attended Faculty development program sponsored by Pharmacy council of India (New Delhi) on "Teaching Regulatory Affairs for M Pharm Programme" which was conducted by JSS College of Pharmacy, Mysuru from 9th april 2018 to 14th april 2018. Topics on generic drug product development, ICH guidelines, regulatory requirements for generics in TGA (Australia), EU (Europe Union), MHRA (united kingdom) and ROW (Rest of the world countries) and Hands-on-Training with Pharma Ready Software was given for eCTD submission. Among the resource persons Mr.A.G.Raghu, director of Santhana Gopala consultants, discussed about Documentation in Pharmaceutical industry involving ALCOA, Master production record etc. Dr.Bobby George, Vice President & Head of Regulatory affairs, Reliance Life Sciences, briefed about clinical trials, protocol, investigational medicinal product dossier, data safety monitoring board etc. Mr. Singaravelan Radhakrishnan, General Manager, Regulatory Affairs and Compliance, Apotex India, Banglore, talked on regulatory requirements for Europe union and he focused on centralized procedure, decentralized procedure, mutual recognition procedure and nationalized procedure. Hands on training for eCTD was given by Navitas lifesciences with Pharma Ready software. About 16 talks were delivered by eminent speakers on regulatory affairs and 15 faculty members from different PCI approved colleges attended the programme.