

GUEST LECTURE ON DRUG FILING AND APPROVAL

Dr Praveen R&D Manager – Drug Development & Scientific Research, SPI PHARMA, Bengalooru on 2nd Sept. 2011 provided a guest lecture indepth knowledge to all students, staff of J.S.S.C.P Mysore and Ooty branch about the **Drug Filing and Approval Process in US and European Union.**



He provided ample of information with his experience in the Pharmaceutical Industries for many years and discussed the following preamble throughout the day.

Morning Session	Afternoon Session
US Drug Filing and Approval <ol style="list-style-type: none">1. Historical Perspective2. US FDA – Organization3. Types of Drug Filing in US4. NDA requirements vs. ANDA requirements5. NDA review process and key milestones6. ANDA review process and key milestones7. CFR requirements for Investigation New Drug applications8. CFR requirements for New Drug application9. Exclusivities granted by the US FDA10. Life after Hatch-Waxman Act11. US FDA resources for Regulators	EU Drug Filing and Approval <ol style="list-style-type: none">1. Drug filing in EU2. Types of Drug Filing in EU3. The National Procedure4. The Mutual Recognition Procedure5. The Decentralized Procedure6. The Centralized Procedure7. Exclusivities granted in EU8. EU resources for Regulators