SRI VENKATESWARA COLLEGE OF PHARMACY

(Autonomous)

Approved by AICTE & PCI, New Delhi, Permanently Affiliated to JNTUA, Ananthapuramu
Accredited by NBA, New Delhi for UG Programme under Tier-II & NAAC, Bengaluru
Recognized under section 2(f) & 12(B) of UGC Act, 1956
Recognized Research Centre for Pharmaceutical Sciences by JNTUA
Recognized In-House R & D by DSIR, New Delhi, DST – FIST Sponsored Institute
Ranked 79th by NIRF 2024 Rankings by MHRD, Govt. of India
RVS NAGAR, TIRUPATI ROAD, CHITTOOR – 517127, A.P.

M.Pharmacy Regulatory Affairs

Course Outcomes

CO1: Student is able to know basics of Medical Devices, IVDs process development ethical and quality consideration.

CO2: To Harmonise the initiatives for approval and marketing of Medical devices and IVDs.

CO3: Know to Regulate approval process for medical devices and IVDs in India, US, Canada, EU Japan and Asia.

CO4: Clinical Evaluation and Investigation of Medical Devices and IVDs

Program Education Objectives

PEO 1: Advanced knowledge and Expertise; Graduates will integrate knowledge of regulatory requirements, guidelines and procedures relevant to pharmaceuticals, medical devices and biotechnology sectors globally and will be able to apply this knowledge to solve complex problems in the field.

PEO 2: Research and Innovation: Graduates will develop advanced skills in preparing and submitting regulatory documents, managing regulatory submissions and ensuring compliance with regulatory standards.

PEO 3: Professional Growth and Lifelong Learning: Graduates will continuously improve their knowledge and skills through life learning, advanced education and professional development, and will contribute to the pharmaceutical sciences community

PEO 4: Graduates will exhibit leadership qualities and the ability to work collaboratively in multidisciplinary teams and uphold the highest ethical standards and professional integrity in their practice ensuring the safety, efficacy and quality of pharmaceutical products while adhering to regulatory requirements.

Program Specific Outcomes

PSO1: Develop expertise in drug regulatory requirements, quality assurance, and compliance with international guidelines such as FDA, EMA, ICH and WHO.

PSO2: Gain proficiency in dossier preparation, patent filing, intellectual property rights (IPR), and regulatory documentation for pharmaceutical products.

PSO3: Acquire skills in Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and risk assessment to ensure pharmaceutical product safety and efficacy.