JSS Academy of Higher Education and Research

JSS College of Pharmacy

Sri Shivarathreeshwara Nagar, Mysuru-570015

List of Adjunct faculty

1. **Dr. Subhash Malghan:** Ex-Deputy Director, CDRH, US-FDA, USA Consultant to Regulated Biotechnology Industry, Washington D.C.

   Expertise in medical devices, pharmaceutical, drug delivery, diagnostic devices, and biotechnology to develop regulatory science and regulatory strategies, R&D planning for product innovation and product development life-cycle, translation of laboratory findings into commercial products, and global regulatory agency process management.

2. **Dr.Vinod P Shah:** Pharmaceutical consultant; a Distinguished Pharmaceutical Scientist and a consultant at USP.

   He was Scientific Secretary (2003 – 2011) of International Pharmaceutical Federation (FIP), and is now Chair of Regulatory Sciences Special Interest Group of FIP. Retired from US FDA (Food and Drug Administration) as a Senior Research Scientist after 30 years of service in July 2005. He has developed several Regulatory Guidances for Pharmaceutical Industry in the area of biopharmaceutics. He has received several FDA Awards including Award of Merit, Scientific Achievement Award and Distinguished Career Service Award.

3. **Dr.GN Singh:** Ex DCGI, Head, Indian Pharmacopoeial Commission, New Delhi

   He is a man of excellent leadership, dedication and commitment to raise the quality of drug regulatory system in the country.
   Dr. G. N. Singh established Indian Pharmacopoeia Commission (IPC) in the year 2009 with aim to set and promote quality standards for drugs and pharmaceuticals in the country. Dr. G.N. Singh, the first Secretary-cum-Scientific Director of the Commission has been discharging the functions and duties of Chief Scientific and Executive Officer till today.

4. **Ms. Sumati Randeo:** Industry's trailblazer with 24 years experience in regulatory, QMS, clinical research, corporate strategies and advocacy New Delhi, Delhi, India.

   Currently handpicked and entrusted with the responsibility of providing subject matter expertise to:
   Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare India ;
   World Health Organization (WHO) SEARO India office and
   Quality Council of India (QCI)

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5. **Dr. Shenaz Khaleeli:** Co Founder & Technical Service Director, PharmaLeaf Private Ltd, Bengaluru

25 yrs of combined Industry and Academia experience in Regulatory, Medical, Clinical, CMC, Audit, Compliance, Marketing, Business Development, Project Management, Patent & Corporate Affairs in Indian, Joint Venture & Multinational Pharmaceutical Companies.

6. **Mr.G Srinivas:** Vice President and Head of Regulatory Affairs, CQA Lead - US Operations, Zydus Pharmaceuticals USA

A highly experienced Pharmaceutical Regulatory Affairs leader with more than 22 years of Pharmaceutical industry experience in terms of Manufacturing, Quality Assurance, Quality Control and US Regulatory Affairs (250 ANDAs / 6 505(b)(2) Submission Experience) who has been guiding organization successfully through USFDA audits.

7. **Dr Jayasheel B G:** Head - Pharmacovigilance & Regulatory Affairs at Alcon, a Novartis company
Physician with 16 years of professional work experience including 3 years of clinical practice and 3.5 years of academic (Clinical Pharmacology) and 10 years in Pharma Industry.

Expert in clinical research with broad experience in most therapeutic area and in various aspects of drug development, clinical development strategy for NCEs & stem cells, medical writing, medical review, CQC, medical monitoring, drug safety & narrative writing, feasibility studies, regulatory affairs, project management, business proposal development, etc. Exposed to Clinical studies of all phases with NCEs, NBEs, including drug-drug interaction studies, Stem cell studies, medical device studies etc.

8. **Mr. Mir Imran Ali:** Senior Vice President and General Manager for Covance Drug Development India

Overall 18 years of experience in Pharmaceutical Industry including over 15 years in Clinical Research, General Management, Clinical Data Management, Drug Safety, Cardiac Safety and Risk Based Monitoring Operations, have managed and delivered several Phase I to IV trials across the globe.