

# SIVA PRAKASH

Result-driven Quality Control Manager with over 14 years of experience in ensuring compliance with industry regulations & standards; expert in leading cross-functional teams, implementing quality systems, and driving continuous improvement initiatives



bio.bsp09@gmail.com; sivaprakashboddu13@gmail.com



+91-9493690098;

## Profile Summary

- An established professional with skills in **managing QC department for Pharmaceuticals & Food verticals**, overseeing quality assurance activities throughout the product lifecycle, from development to commercialization
- Expert in implementing and **maintaining quality systems, including SOPs, change control, deviations, and CAPAs**, resulting in reduction in deviations and increase in compliance
- **Provided training and guidance to staff on quality systems**, regulations, and best practices, contributing to a culture of quality and continuous improvement
- Distinguished proficiency in **spearheading continuous improvement initiatives**, identifying areas of non-compliance, and implementing corrective and preventive actions
- Remarkably **completed IRCA registered ISO 9001:2015 QMS Lead Auditor Training Course** conducted by TUV Nord India Pvt. Ltd.
- Showcased excellence by **conducting regulatory audit for clients like USDFA, WHO, BRC, EIA and customer audit for Dr. Reddy's. and internal audit for GQM**
- Subject matter expertise in **collaborating with R&D and Manufacturing teams** to ensure seamless product transfer and scale-up while maintaining quality standards
- Possess strong **leadership qualities, excellent problem-solving abilities**, and a commitment to delivering projects of highest quality

## Education

- M.Sc. (Biotechnology) from KKECS College of Science & Technology (Bangalore University), Bengaluru in 2008
- B.Sc. (Biotechnology, Biochemistry, Chemistry) from N.N.S. Vidya Degree College (Nagarjuna University) in 2006

## Trainings Attended

- Participated in the following training programs:
  - Antibiotic Analysis by automatic ELISA using Chem well by R-Biopharm (Neugen Diagnostics)
  - Antibiotic Analysis by Elisa Reader Technique by Randox Diagnostics, Hyderabad
  - ISO 22000:2005 for Food Safety conducted by SGS India Pvt. Ltd.
  - HACCP conducted by Safe Food Solutions

## Core Competencies

Quality Assurance

Risk Assessment & Management

Regulatory Compliance (cGMP)

Validation & Qualification

Quality Management Systems

Project Coordination & Execution

Continuous Improvement

Cross-functional Collaboration

## Organizational Experience

Since Jun'23 with Sanzyme Biologics Pvt. Ltd. as Deputy Manager - Quality Control

**Nov'21 – Jun'23 with Brilliant Bio Pharma Pvt. Ltd. as Assistant Manager - Quality Control**

**Aug'20 – Nov'21 with Dr. Reddy's Lab, Hyderabad as Team Lead / QC Microbiologist**

**Apr'15 – Jul'20 with Poultry Diagnostics & Research Center of Venkateshwara Hatcheries Pvt. Ltd. (VHPL), Hyderabad as Technologist**

**Jan'11 – Mar'15 with DEVI Sea Foods as EIC approved Technologist**

**Jan'09 – Dec'10 with MPEDA ELISA Screening Laboratory (Govt. of India) undertaken by Sea Lab as Junior Technical Officer**

**Key Result Areas: Please confirm the following points**

- Assisting in the development of quality control procedures & systems, leading to reduction in defects
- Conducting thorough investigations into deviations, CAPAs, and customer complaints, identifying root causes and implementing corrective actions
- Collaborating with cross-functional teams to ensure proper documentation, testing, and release of pharmaceutical products
- Supporting the qualification & validation of manufacturing equipment, ensuring compliance with industry standards
- Providing training to Manufacturing & Quality control teams on quality systems and regulatory requirements
- Performing analytical testing & quality control assessments on raw materials, in-process samples, and finished products while ensuring compliance with established specifications and standards
- Reviewing the daily analysis and ensuring the laboratory compliance with respect to cGMP and GLP

## Technical Expertise

- Developing the MOA (Method of Analysis) for testing the product
- External Audits like ISO, FSMS (22000), HALAL & Kosher
- Maintenance of the cell lines BHK Mono, Vero Cell Lines & BHK CZ and Cell Suspension
- Potency Test by Serum Neutralization test (SNT)
- Foot and Mouth Virus (FMD), Rabies Virus (RV), Blue Tongue Virus (BT) Titres using ELISA Technique
- Mycoplasma detection by PCR Technique
- Rabies Virus Titre checked by Immunofluorescence Assay
- Quantification of 146S virus detected by Chromatography Technique
- Microbiological Analysis of water sample & finish product (Pour Plate Method and Filtration Method)
- Autoclave Validation
- Implementation of the water MLT & MLT for finished product in LIMS

## Personal Details

**Date of Birth:** 13 April 1984

**Languages Known:** English, Telugu, Hindi and Kannada

**Present Address:** B Plot No. 712, S.K.D. Nagar, Vanasthalipuram, Hyderabad - 500070, Telangana, India

**Permanent Address:** S/o BABU, Opposite Vijaya Hospital, Sipoypet, Chirala (M) Prakasam (District) – 523155, Andhra Pradesh, India