

Srinivasa Rao P. MSc-Microbiology.
Deputy General Manager – Quality Assurance



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Summary

- Quality Assurance professional with over 20 years of experience in the pharmaceutical industry. Deep understanding of Good Manufacturing Practices (GMP) and regulatory compliance. Proven track record in developing and implementing quality systems to ensure product safety and efficacy. Strong leadership skills with the ability to effectively manage teams and drive continuous improvement initiatives. Committed to maintaining the highest quality standards and ensuring compliance with industry regulations.

Expertise

- Ensured cGMP site compliance of policies and procedures throughout the organization for the manufacture of aseptic area for injectable and parenteral products while providing in - process decision making.
- Enforced compliancy of corporate Policy, Quality Agreements, Confidentiality Disclosure Agreements, and approved Technical Reports, Analytical Test Methods, conducted Product Process Validation investigations and Product Batch Record disposition status.
- Responsible for remediating product complaints, Quality Systems, SOP's and monitored performance efficiency to Change Control, Deviation/CAPA, and Document management.
- Executed cGMP audits of facility and supplier vendors for adherence to regulatory (FDA, EU) expectations.
- Primary Sr. Management contact for FDA and customer inspection audits. Ensured company is continually in a state of cGMP inspection readiness by driving accountability of all applicable cGMP regulations across departments.
- Interacting with the Agency for Medicines US-FDA, FIMEA(EU), WHO Geneva, MHRA, Anvisa and other global regulatory bodies.
- I am a self-esteemed and amicable person with positive approach. I am an effective team player with good knowledge on pharmaceutical operations, and have in-depth understanding on their inherent complexities, with great stride for compliance.

Experience – Total 20+ Years:

8. Aurobindo Pharma-Unit-XII: Feb-2016 to till date

Aurobindo Pharma became a public company in 1992 and listed its shares in the Indian stock exchanges in 1995. In addition to being the market leader in SemiSynthetic Penicillins, it has a presence in key therapeutic segments such as neurosciences, cardiovascular, antiretrovirals, antidiabetics, gastroenterology and cephalosporins, among others.

Regulatory Exposure: Directly interacted with regulatory audits like US-FDA, FIMEA (EU-GMP), Anvisa(Brazil), South Africa-MCC and other customer audits.

Responsibilities (Site QA – Dy. General Manager):

- Managed QA teams integrating sterile & Non-Sterile products providing cGMP compliance in handling, manufacturing, filling and packaging as per EU, ICH and FDA 21 CFR.
- Overseen validations of equipment, Facility qualification and Serialization strategies.
- Authored, reviewed and approved GMP documentation; SOP's, Batch Records, Investigations, Validation deliverables FMEA's, Risk Assessments,
- Managed Quality System Change Control / CAPA program along with performance indicators/metrics/KPI's, AQL sampling for inspection and managed APR Quality review of commercial products.
- Assessed quality impact of product using statistical analysis tools due to nonconformance specifications

(Process Pad).

- Investigated unresolved non-conformance manufacturing issues and CAPA's identified in audits.
- Re-evaluated product disposition status, determined "root cause" evaluating impact of deviation on final product disposition and identifying risk to previous product lots using statistical tools.
- Identified trends within deviations/investigations causing excursions interfering with product disposition.
- Report to top management on the performance of the QMS, Internal audit, Compliance level, ongoing projects and any need for improvement.
- Ensure the promotion of awareness of customer requirements throughout the organization.
- Liaise with the external assessment body on all matters related to the external accreditation process.
- Overseeing all third party and loan licensing cGMP & cGLP aspects as a lead auditor.
- Lead investigator all investigations and identify proper root cause and implement the CAPA and verify their effectiveness periodically.
- Having a team of 75 quality associates responsible for all IPQA, QMS & Validation related activities.

7. Manager QA - Brilliant Bio Pharma Pvt. Ltd.: June-2014 – Jan-2016

Brilliant Bio Pharma Limited (BBPL) is a member company of 226 million US\$ TGV conglomerate engaged in manufacture of Veterinary Biologicals and Medicines at Hyderabad to manufacture and market Veterinary Biologicals & Medicines with the State-of-Art facility.

Regulatory Exposure: National level GMP by CDSCO, WHO GMP, GLP & ISO 9001:2008

Responsibilities (Site Quality Head):

- Devising and establishing a company's quality procedures, standards and specifications.
- Reviewing customer requirements and making sure they are met.
- Working with purchasing staff to establish quality requirements from external suppliers.
- Setting standards for quality as well as health and safety;
- Making sure that manufacturing or production processes meet international and national standards.

6. Manager QA – MEDREICH LIMITED: September 2013- May 2014 (08 months)

Medreich is a fully integrated pharmaceutical company with an established presence across the globe. Unit-V facility based in Hyderabad (India) is capable of manufacturing both oral and sterile dosage forms of cephalosporins. This facility is also self-sufficient in all areas of manufacturing, procurement of materials, quality control and assurance, engineering, and logistics. I am responsible for Quality head for unit-V.

Regulatory Exposure: International : MHRA & ANSM, GCC(Gulf Co-operation Council), & Kenya

National level : GMP by CDSCO, WHO GMP,

Responsibilities (Site Quality Head):

- Ensuring the procedures and specifications of firms under contract are also appropriate and followed, i.e., maintain control and take responsibility for third-party services providers (contract manufacturers, contract laboratories, etc.)
- Ensuring appropriate manufacturing in-process controls are implemented
- Ensuring in-process controls are performed during manufacturing operations and maintain consistently with satisfactory results. Etc.

5. Manager QA - Shantha - A Sanofi Company: September 2011 - September 2013 (2.1 Years)

I am responsible for organizing, delivering, documenting and evaluating training for technical and management staff related to technical/scientific skills, local/departmental tasks, regulatory skills, general industry expertise. Utilization of current and new learning techniques, training styles focusing on the professional adult learning environment was implemented.

Regulatory Exposure: International : WHO (Geneva)

National level : GMP by CDSCO, WHO GMP & ISO 9001, 14001 & 18001.

Responsibility(Training and Education Manager):

- Plays a key role in effective design, coordination and presentation of training, Professional development and continuous learning for Shantha- Sanofi staff.
- Working directly with the organization's subject matter experts to gain information needed to create comprehensive training programs.
- Delivering training to staff of all levels on-site and using a variety of instructional techniques including interactive lectures, group discussions, team exercises, Webinars and videos, etc.

- Conducts needs assessments to determine strategic measures required to enhance employee job performance. Etc.

4. Quality Expert at PYMEPHARCO -Vietnam under STADA-AG: Aug. 2010 - July. 2011 (01 Year)

PYMEPHARCO is a renowned Vietnam based company, with a major stake of STADA AG, involved in manufacture of various pharmaceutical dosage forms. I had been working in a consulting role at PYMEPHARCO, on behalf of STADA AG, in up gradation of their facilities and quality systems for approval by EU and other global regulatory agencies.

Regulatory Exposure: International : EU-GMP

Key Performance Indicators:

- Achieving the EU-GMP for oral solids and Sterile dry powder Blocks.
- Involving all activities like engineering, production ,QC, Ware house ,safety and implementation of Quality systems.

3. Asst. Manager in QA at Dr.Reddys laboratories – FTO-I (IPQA): Aug.2008 - June 2010 (2 year)

I am leading the IPQA functions of Dr.reddys FTO unit-I, located in Hyderabad, intended for manufacture of sterile formulations in various dosage forms (Vial/ Ampoule injections). I am championing various activities associated with IPQA process of the product and involving in facility, equipment, personnel qualifications/ validations.

2. QA at Indian Immunologicals Limited (IPQA): June 2006 - July 2008 (2.2 years)

I have been working as a QA for it's vaccines division and responsible for implementation/ assurance of quality & compliance attributes across the division. Also my role is vital in other technical functions for the overall growth process, implementation/ assurance of quality & compliance attributes.

Responsibility

QA activities Involve from the Biological process, starting from Production of cell culture→Infection→Harvesting→viruspool→Clarification→Blending→Filling process to dispatch

1. Microbiologist at Cipla (Unit-IX, Goa-Verna) : May 2003 - June 2006 (3 years 2 months)

I had been working as microbiologist in microbiology lab QC, which was involved routine microbiological testing of a sterile pharmaceutical facility/ products. I was extensively involved determining various process attributes and validations.

PROFESSIONAL CONTRIBUTIONS & ACHIVEMENTS:

- Key contribution in implementation of Quality Management Systems.
- Trained on 5S & Other TQM Tools (Quality excelency, waste reduction, OEE, etc) concept.
- Involved in regulatory audits MHRA, WHO(Geneva), GCC, ISO, ANVISA, FDA, GCC.
- I had undergone internal & External GMP training programs related to sterile activities and PDA programs.
- In Pymepharco-Vietnam faced and successfully achieved EU-GMP(Germany)

❖ **I am a certified Trainer and auditor by NSF-DBA**

Computer Skills:

- Oracle bases related transactions (ERP).
- Training system online (Epic Learning)
- QMS-online (Metric system)

Academics:

- **M.Sc, Microbiology** in 2001 - 2003 (63%) at Swami Ramanandha teerth maratwad university, Nanded (Maharashtra).
- **B.Sc, Microbiology** in 1998 - 2001 (72.5%) at Nagarjuna University.
- Intermediate in 1996 - 1998 (62%).
- SSC in 1996 (64%).

Personal Profile:

Father's Name : P.PARTHA SARADHI
 Marital Status : Married
 Languages Known : English, Telugu, and Hindi
 Permanent Address : P Srinivasa Rao,
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I declare that the above given information is correct to the best of my knowledge and belief.