Nagalla Sekhar Babu

Assistant Manager-QA

Mobile No: 9963616863 **Email Id:** sekharnagalla@gmail.com **Address:** Suryapet **DOB:** 12/06/1982
LinkedIn: https://linkedin.com/in/sekhar-babu-nagalla-83643419

As a certified quality assurance professional in the pharmaceutical industry, I am dedicated to enhancing product excellence with expertise in implementing robust Quality Management Systems (QMS), ensuring compliance with cGMP/GDP standards, and leading successful quality improvement initiatives, I work to exceed regulatory and customer expectations. My goal is to cultivate a culture of continuous improvement and innovation, contributing to the delivery of high-quality active pharmaceutical ingredients and intermediates.

Professional Summary

- Extensive expertise in quality assurance, regulatory compliance, and internal auditing within the pharmaceutical industry, ensuring adherence to global standards and continuous improvement across manufacturing and operational processes.
- Proficient in managing and optimizing Quality Management Systems (QMS), including change, deviation, and incident management.
- Experienced in conducting internal audits, overseeing external audits, and ensuring effective CAPA follow-up.
- Skilled in cGMP/GDP/Data Integrity implementation and monitoring throughout the product life cycle.
- Proven track record in managing technology transfers, project quality, and risk management studies.
- Leadership capabilities demonstrated by effectively directing a team of QA professionals towards collaborative success.
- Strong commitment to regulatory compliance, customer satisfaction, and the pursuit of best practices in quality assurance.

Soft Skills

- Effective Communication
- Strategic Planning
- Leadership
- Problem Solving
- Team Collaboration

Technical Skills

- Training Management Systems (TMS)
- Vendor Management
- Document Management Systems (DMS)
- CAPA Management
- Internal & External Auditing
- GDP / Data Integrity

Core Competencies

- Quality Assurance
- Quality Management Systems
- Process Improvement
- Regulatory Compliance
- Change Management

Work Experience

May 2025 - Present

Assistant Manager - QA

Cohance Life Sciences Limited (Suryapet)

Experienced in quality assurance, compliance, and auditing in the pharmaceutical industry.

• Handling of internal audits and external audits, Follow up of CAPA regarding audit observations as per the committed timelines.
• Managed customer inquiries and requirements within the target time period.
• Implemented and monitored various quality management systems including change management, deviation management, and incident management, OOS/OOT Management.
• QMS Trending and CAPA effectiveness verification.
• Conducting mock recalls as per the timelines.
• APQRs Review and follow up recommendations.
• Trained and empowered QA team for effective collaboration and problem-solving.
• Oversaw product release and distribution processes.
• Monitoring Vendor qualifications including KSM, Critical materials and packing materials.
• Conducting Vendor Audits and prepare audit reports and follow up CAPA on audit observations.
• Timely follow up and getting quality agreements with vendors.
• Ensured effective implementation and monitoring of cGMP/GDP/Data Integrity throughout the product lifecycle.
• Reviewed and approved standard operating procedures (SOPs), Batch records, validation & qualification protocols & reports, Analytical Records.
• Review the Master Validation Plan and tracker.
• Led successful technology transfers and quality risk management studies.
• Closely working with CFTs and guide them whenever required.
• Responsible for Monthly QMS data presentation to Head quality.

Achievements:
• Successfully handled multiple system implementations such as Document Management Systems and Training Management Systems.
• Led a team in achieving compliance with regulatory standards and fostering a culture of continuous improvement.
• Zero customer complaints.

Jan 2020 - Apr 2025

Assistant Manager - QA

Suven Pharmaceuticals (Suryapet)

Experienced in quality assurance, compliance, and auditing in the pharmaceutical industry.

- Conducting internal audits and Handling of external audits, CAPA, and follow-ups
- Managed customer inquiries and requirements
- Implemented and monitored various quality management systems including change management, deviation management, and incident management
- Trained and empowered QA team for effective collaboration and problem-solving
- Oversaw product release and distribution processes.
- Monitoring Vendor qualifications including KSM, Critical materials and packing materials.
- Timely follow up and getting quality agreements with vendors
- Ensured effective implementation and monitoring of cGMP/GDP/Data Integrity throughout the product lifecycle
- Reviewed and approved standard operating procedures (SOPs), Batch records and validation protocols
- Led successful technology transfers and quality risk management studies

Achievements:

- Successfully handled multiple system implementations such as Document Management Systems and Training Management Systems
- Led a team in achieving compliance with regulatory standards and fostering a culture of continuous improvement

Apr 2011 - Dec 2019

Senior Executive - QA

Suven Life Sciences Ltd. (Suryapet)

Contributed to the management and improvement of quality assurance practices.

Participated in compliance and auditing activities
Involved in handling customer complaints and managing vendor relationships
Played a key role in quality assurance processes
Supported implementation of quality management systems

Achievements:
Participated in the development and improvement of internal audit processes
Assisted in maintaining cGMP/GDP/Data Integrity standards

Aug 2003 - Mar 2011

Officer-QA (Information Technology)

Suven Liesciences Limited (Suryapet)

System maintenance and support, User assistance, Network and security management, IT systems policy implementation, Data back up and restoration.

Computer systems maintenance.
Software and hardware issues resolving
User problems rectification
Networking & security activities (internet and antivirus software)
Reporting to IT Head office on daily issues and resolves.
Computer system data back and restoration when needed.

Achievements:
Maintaining the systems with error free.
Timely data back and restoration without audit observations

Education

MSc-TQM
Sunrise University, Alwar
(Jan 2024 - Jan 2026)

Bachelor of Computer Sciences
Acharya Nagarjuna University
(Jun 2000 - Jun 2003)

Intermediate, MPC
Dr. B.R.Ambedkar College
(Jun 1998 - Apr 2000)

Advanced Diploma in Quality Management
INDIAN INSTITUTE OF SKILL DEVELOPMENT PRIVATE LIMITED
(Oct 2023 - Dec 2023)

Achievements

- 1. Successfully implemented GMP / GDP and Data Integrity practices in all the CFTs.

2. Successfully launching and completion new projects with CFTs and on time documentation and successfully delivered products to customers within timeline.
3. Received reward and reorganization from management for three recent projects.
4. Successfully led quality assurance for multiple product launches, ensuring zero deviations from regulatory standards.
5. Participating in documents reviews during Regulator audits at other group sites.

Certifications

- **Certified Total Quality Management Professional** (Issued by ISEL GLOBAL - Six Sigma Certification & PMP Certification Institute - 2023)
- **Certified Lean Six Sigma Black Belt (LSSBB)** (Issued by OTIFAS - 2023)

Hobbies

Volunteering in community health initiatives, Learning new things

Languages

English, Telugu, Hindi