

SAMBASIVA RAO MUTYALA

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CAREER OBJECTIVE

A dedicated Quality professional with over 12 years of pharmaceutical experience, seeking to contribute expertise in Quality Assurance, Quality Control and Quality Systems to a leading organization, while continuing to grow professionally and support organizational excellence

PROFESSIONAL SUMMARY: 12+ years / Assistant Manager.

Organization	Role & Department	Duration
Biological E. Ltd – Vaccines Division, Hyd	QA Systems & Compliance - QMS Coordinator (Deviation, Change controls, OOS, Incidents) - Internal Auditor - Qualified GMP Trainer QC-QMS & Training co-ordinator	Dec 2022 – Present
Lupin Ltd, VZG	QMS / Investigations - Reviewer for Deviations, Change Controls, OOS, and Incidents	Nov 2021 – Nov 2022
Cronus Pharma Ltd, Hyd	QC– Reviewer & QMS Coordinator - Reviewer of QC data - QMS Coordinator (Incidents, Deviations, Change Controls, OOS, etc.)	Jun 2020 – Nov 2021
Gland Pharma Ltd, Hyd	QC Department – Analyst Analysis of raw materials, finished products, and stability samples - Hands-on with HPLC, method validations, and lab compliance	May 2013 – Mar 2020

QA System & Compliance: (QMS & Training)

- Handling & Review of QMS elements like Deviations, **Incidents, OOS, CAPA, and Change Control.**
- Participated in QMS investigations and contributed to **root cause analysis, hypothesis protocol creation, and CAPA implementation.**
- Conducted **trend analysis of deviations and incidents**, supporting continuous improvement efforts.
- Maintained **analyst qualification tracking** and ensured timely requalification in LMS.
- Reviewed and updated **SOPs** in line with audit observations and regulatory changes.

- Acted as **GLP Coordinator**, ensuring laboratory practices were compliant with internal and external quality standards.
 - Verified **data integrity** of chromatographic results using **Empower** and **Chromeleon** software.
 - Reviewed **audit trails, instrument logs, HPLC calibration records, and e-logbooks** for accuracy.
 - Managed **document change requests** and implemented CAPAs to prevent repeat occurrences.
 - **Managed complete training lifecycle** including QA Induction, Initial GMP Trainings, On-the-Job (OJT), Refresher Trainings, and both Internal and External training programs.
 - **Enterprise Training Coordinator (ETC)** Oversaw user group assignments, all department curriculum management, SOP linking, and scheduling of all training types (initial, periodic, re-trainings).
 - Ensured **zero overdue SOP trainings** across all departments & 4 sites on a monthly basis.
 - Led **internal walkthroughs and audits** to uphold lab compliance and ensure all-time audit readiness.
 - Maintained and updated specimen signature records, job descriptions, and departmental organization charts (organograms).
 - Created and monitored the **Annual Training Calendar**, ensuring timely completion of mandatory trainings.
 - Developed and delivered **GMP training modules** with integrated assessments and effectiveness checks.
 - Supported the **CSV team** in LMS validation, compliance checks, and system performance reviews.
 - Coordinated and organized **external training sessions, webinars, and virtual learning events** to foster continuous professional development.
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Quality Control (Analyst Role):

- Conducted analysis of raw materials, finished products, and stability samples.
 - Performed analytical method validations and method transfer activities.
 - Handled in-process sample analysis during batch filling (top, bottom, flush, stroke samples), including BTS, ATS, and D-TS.
 - Executed analytical tests such as Assay, Related Substances, Chromatographic Purity, and Preservatives using HPLC.
 - Conducted working standard qualification and maintained control of working standards and impurities.
 - Specialized in ophthalmic solution analysis and maintained lab compliance with GLP and cGMP standards.
 - Documented online entries in instrument/equipment logbooks, standard consumption logs, and column logs.
 - Managed laboratory inventory including chemicals, glassware, and HPLC columns.
 - Ensured strict compliance with SOPs, Health & Safety regulations, and GMP documentation standards.
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AWARDS & ACHIEVEMENTS

- **BE STAR Award (2025)**
Recognized for consistently delivering performance beyond the regular scope of responsibilities, demonstrating dedication, ownership, and proactive support in daily operations.
 - **Process Improvement– LMS Upgradation**
Successfully led the in-house Upgradation of the Learning Management System (LMS) across the Vaccine Division, resulting in a cost saving of ₹64 lakhs. Recognized for driving continuous improvement and contributing to operational efficiency and organizational growth.
 - **BE GEM Certificate (2023)**
Awarded for maintaining continuous QC laboratory compliance and ensuring audit readiness at all times, with zero critical observations during internal and external audits
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AUDITS FACED:

- Successfully participated in regulatory and customer inspections, including WHO, USFDA, MHRA, ANVISA, CDSCO, TFDA (Uganda), and multiple client audits.
 - Acted as Subject Matter Expert (SME) during inspections, representing investigation processes, training workflows, and compliance practices.
 - Demonstrated strong technical expertise by explaining HPLC integrations, data review, and reporting procedures directly to USFDA auditors (Feb 2017)
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APPLICATIONS HANDLED:

- TRACKWISE / QAMS (QMS applications)
 - LMS / Nichelon / SABA (Training Applications)
 - DMS
 - Caliber LIMS
 - Empower 3, Chromeleon, Lab Solutions (Chromatographic Software)
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ACADEMICS

- M.Sc. in General Chemistry, Acharya Nagarjuna University (2013–2015)
 - B.Sc. (MPC), Andhra Loyola College, Krishna University (2011–2013)
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PERSONAL DETAILS

- Date of Birth: 02.10.1992
- Languages: English, Telugu, & Hindi
- Nationality: Indian

- Marital Status: Married
 - Permanent Address:
S/O M.V Seshadri Rao,
Krishna District, Vijayawada, A.P., India - 520007
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DECLARATION

I hereby declare that all the statements made in this application are true and correct to the best of my knowledge and belief.