Dr. A. NARAYANA

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Deputy General Manager (Head-QA & In Charge Quality)

*Results-driven Quality Assurance leader with **nearly 25 years** of experience in pharmaceutical quality systems and regulatory compliance. Targeting a senior leadership role to leverage expertise in QA, audit management, and team development to drive continuous improvement and ensure global compliance within a leading pharmaceutical organization.*

PROFILE SUMMARY

- **Experienced Quality Assurance Strategist** with progressive experience in leading QA/QC functions, ensuring global regulatory compliance, and elevating quality frameworks across API manufacturing environments.
- **Regulatory Compliance Expert**, proficient in handling inspections by US FDA, WHO GMP, and Written Confirmation authorities; adept at preparing audit responses and implementing CAPA with high effectiveness metrics.
- **Enterprise Quality Architect**, driving **ISO 9001:2015** implementation and harmonizing Quality Management Systems across multiple units, while acting as Management Representative for continual quality advancement.
- **Cross-Functional Leader**, managing site-wide QA operations, batch release, process validation, and quality risk assessments while spearheading cross-border contract manufacturing partnerships with global clients like **Corbion Purac**, **Netherlands & Bayer** for APIs and intermediates.
- **Proficient in Technology Transfers & Product Launches**, steering scale-up, validation, and commercialization through rigorous document review, deviation handling, and root cause analysis.
- **People-First Leadership Approach**, building high-performing QA teams, delivering GMP/cGMP training, and fostering a culture of continuous improvement and regulatory discipline.

CORE COMPETENCIES

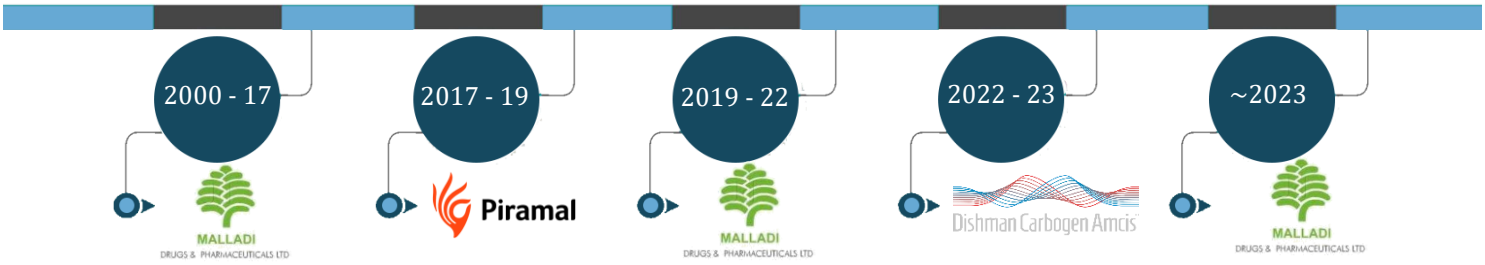
Quality Assurance Leadership	Regulatory Compliance	US FDA Inspection
ISO 9001:2015 Implementation	Process Validation	BPR & BCR Maintenance
CAPA Management	Change Control Management	Vendor Qualification
Stakeholder Engagement	Contract Manufacturing Oversight	Risk Assessment & Mitigation
Regulatory Affairs Support	Team Development & Training	Quality Management Systems

SOFT SKILLS

EDUCATION

- **Ph.D. in Chemistry** from Sri Venkateswara University, Tirupati
- **M.Sc. in Chemistry** from Kuvempu University, Karnataka
- **B.Sc. in MPC** from Sri Venkateswara University, Tirupati

CAREER TIMELINE



WORK EXPERIENCE

Jan'23 – Present | Deputy General Manager (Head-QA & In Charge Quality) | Malladi Drugs & Pharmaceuticals Ltd. Unit-5 (Malladi Group), Tirupati

Aug'22 – Jan'23 | Assistant General Manager (Head-QS) | Dishman Carbogen Amcis Limited, Ahmedabad

Feb'19 – Aug'22 | Assistant General Manager (Head-QA) | Malladi Drugs & Pharmaceuticals Ltd. Unit-5 (Malladi Group), Tirupati

May'17 – Feb'19 | Manager – QA | Piramal Enterprises Limited, Chennai

Jan'00 – May'17 | Malladi Drugs & Pharmaceuticals Ltd. Unit-5 (Malladi Group), Tirupati
Growth Path: Trainee → Jr. Officer → Officer → Sr. Officer → Asst. Manager – QA

Key Result Areas Throughout the Career:

Quality Leadership & Governance:
- Managing site-wide QA operations as a senior leadership team member, contributing to operational success & regulatory excellence.
- Harmonizing quality system procedures across units and acting as the Management Representative for ISO 9001:2015.
- Designing and updating QMS documentation, SOPs, and GMP records to align with global quality standards.

Regulatory Compliance & Audit Management:
- Coordinating & representing the site during regulatory audits (US FDA, WHO GMP, Written Confirmation) & customer inspections.
- Preparing audit responses, tracking CAPA implementation, and reviewing effectiveness of corrective actions.
- Conducting internal audits as per schedule and ensuring closure of audit observations.

Vendor Qualification & Contract Manufacturing:
- Planning and executing vendor qualification activities including supplier evaluation, site audits & compliance verification.
- Overseeing contract manufacturing operations with partners like Corbion Purac and Bayer, including audit coordination and document review (change control, OOS, deviations).

New Product Launch & Technology Transfer:
- Reviewing technology transfer documents and coordinating new product scale-up, validation batch execution, and product regularization.
- Preparing/reviewing scale-up and validation protocols and ensuring seamless execution across departments.

Process & Cleaning Validation:
- Leading the preparation, review, and approval of validation protocols for processes, equipment, and cleaning.
- Monitoring execution of qualification activities for cleanrooms, water systems, HVAC, and facility infrastructure.

Deviation, OOS & Complaint Handling:
- Handling deviations, out-of-specifications (OOS), and customer complaints by conducting root cause investigations.
- Driving timely CAPA implementation and evaluating effectiveness through follow-ups and internal audits.

Change Control & Risk Management:
- Implementing and monitoring an effective Change Control System with impact analysis, approvals, and risk mitigation.
- Conducting periodic risk assessments and initiating appropriate action plans to reduce quality risks.

Training & cGMP Compliance:
- Delivering site-wide cGMP training, on-the-job coaching, and skill development sessions for QA and cross-functional teams.
- Monitoring training effectiveness and ensuring role-based competency across the workforce.

Documentation & Records Management:
- Reviewing and approving master batch records, validation documents, APQRs, and site master files.
- Overseeing document issuance, retrieval, archiving, and ensuring data integrity in all GMP-related documentation.
- Reviewing ongoing stability studies and providing trend reports to senior leadership.

Regulatory Support & Licensing:
- Supporting preparation and filing of Drug Master Files (DMF), annual updates, and response to regulatory deficiencies.
- Coordinating with drug authorities for obtaining and renewing manufacturing licenses, WHO GMP, EU GMP certifications, and NOCs from CDSCO.

Dispatches & Product Returns:
- Planning & monitoring product dispatches as per client commitments & timelines, while maintaining quality assurance protocols.
- Handling returned goods and salvaging activities as per standard procedures.

Team Development & People Management:
- Leading and mentoring QA teams to build a culture of quality ownership and regulatory preparedness.
- Driving performance through structured training, motivational leadership & continuous feedback on GMP standards & safety.

PERSONAL DETAILS

Date of Birth: 02nd July 1978 || **Languages Known:** English, Tamil & Telugu || **Address:** Tirupati – 517503, Andhra Pradesh || **Passport No.:** U2200148