LOGASHINI K R

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Career Objective

Biomedical Engineer with practical experience in medical device **Quality Assurance**, specializing in **ISO 13485:2016**, QMS documentation, document control, SOP development, complaint handling, CAPA, PMS, and finished product testing. Passionate about ensuring product quality, regulatory compliance, and continuous process improvement.

Professional Experience

Quality Assurance Trainee | Janitri Innovations March 2026 – Present | Bengaluru

- Developed, reviewed, and maintained **20+ Quality Management System (QMS) documents**, including **Standard Operating Procedures (SOPs)**, work instructions, forms, logs, and records in compliance with **ISO 13485:2016** requirements.
- Performed **Document Control** activities, including document review, revision control, version management, issuance, and maintenance of controlled quality documents.
- Reviewed and updated **medical device user manuals** to ensure compliance with regulatory requirements, approved product specifications, and usability requirements.
- Reviewed **primary and secondary product labels** to verify compliance with approved artwork, product specifications, and applicable regulatory requirements.
- Performed **finished product inspection, testing, and verification** to ensure compliance with predefined quality specifications before product release.
- Monitored **manufacturing processes** to ensure compliance with approved procedures.
- Performed **monthly complaint trend analysis** by reviewing customer complaints, identifying recurring quality issues, and supporting **continuous quality improvement** initiatives.
- Raised and documented **Non-Conformance Reports (NCRs)** and supported **Corrective and Preventive Action (CAPA)** activities for investigation, documentation, and closure of quality issues.
- Supported **Post-Market Surveillance (PMS)** activities through complaint data review, PMS documentation, and post-market quality trend analysis.
- Contributed to the preparation and revision of quality procedures for **Complaint Handling, Post-Market Surveillance (PMS), NCR, CAPA, Field Safety Corrective Action (FSCA), Product Recall,** and **Regulatory Reporting**.
- Reviewed **calibration certificates**, verified the calibration validity of inspection and testing equipment before use, and maintained calibration schedules and records to ensure equipment compliance with **ISO 13485:2016** and internal quality requirements.

RAQA Intern | Multi Use Medical Devices November 2025 – February 2026

- Supported **Quality Management System (QMS)** activities by developing, reviewing, and formatting **Standard Operating Procedures (SOPs)** in alignment with internal guidelines
- Assisted in **risk management documentation**, including collection and organization of hazard-related data for medical devices
- Supported **risk estimation and evaluation** activities using predefined criteria under supervision
- Maintained controlled documentation and structured records to support **regulatory compliance and audit readiness**

Certifications

ISO 13485:2016 for Medical Devices - Udemy | 2025

ISO 13485:2016 Internal Auditor Training – Zenith Quality Assessors| 2026

TECHNICAL SKILLS

- Quality Management Systems (QMS) Documentation
- SOP Development & Document Control
- NCR & CAPA Support

Education

B.E Biomedical Engineering 2021 – 2025 | Coimbatore
Dr.N.G.P Institute Of Technology
CGPA 8.4