LOGASHINI K R

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Career Objective

Biomedical Engineer with hands-on experience in Medical Device Quality Assurance, with practical knowledge of **ISO 13485:2016**, QMS documentation, document control, SOP development, finished product inspection and testing, NCR, CAPA, complaint handling, and Post-Market Surveillance. Seeking to contribute to a medical-device manufacturing organization by supporting quality compliance, product quality, and continuous improvement initiatives.

Professional Experience

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

- 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.
- Developed, reviewed, and maintained 20+ QMS documents, including SOPs, work instructions, forms, logs, and records in compliance with **ISO 13485:2016**.
- Performed Document Control activities, including document review, revision control, version management, issuance, and maintenance of controlled quality documents.
- Raised and documented **Non-Conformance Reports (NCRs)** and supported **CAPA** activities for investigation, documentation, and closure of quality issues.
- Performed monthly **complaint trend** analysis by reviewing customer complaints, identifying recurring quality issues, and supporting continuous quality improvement initiatives.
- Supported PMS activities through complaint data review, PMS documentation, and post-market quality trend analysis.
- Performed **supplier performance monitoring** by reviewing PO compliance, delivery timelines, COA availability, and other defined requirements, and assigned supplier performance scores to support supplier evaluation and review.
- Reviewed **calibration** certificates, verified calibration validity of inspection and testing equipment before use, and maintained calibration schedules and records.
- Reviewed and updated medical-device user manuals and product labels for compliance with approved specifications and applicable regulatory 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

- ISO 13485:2016
- Document Control
- SOP & Work Instruction Development
- Finished Product Inspection & Testing
- Manufacturing Process Compliance
- NCR & CAPA
- Complaint Handling & Trend Analysis

Education

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