LOGASHINI K R

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Career Objective

Biomedical Engineer with hands-on experience in medical device Quality Assurance and Regulatory Affairs. Familiar with ISO 13485:2016, QMS documentation, SOPs, complaint handling, Post-Market Surveillance, and quality activities. Seeking to contribute to quality and regulatory compliance while developing expertise in the medical device industry.

Professional Experience

Quality Assurance Trainee | Janitri Innovations March 2026 – Present

- Supported **Post-Market Surveillance (PMS)** activities through complaint review, data analysis, documentation, and quality trend monitoring.
- Reviewed customer complaints and performed **monthly complaint trend analysis** to identify recurring product and quality issues.
- Supported **QMS documentation** activities, including preparation, review, and maintenance of SOPs, work instructions, forms, logs, and records in alignment with ISO 13485:2016.
- Supported **finished product inspection, testing, and verification** against defined quality specifications before product release.
- Reviewed **medical device labels and user manuals** against approved specifications and applicable regulatory requirements.
- Supported **calibration activities** by reviewing calibration certificates and maintaining calibration schedules and records for inspection and testing equipment.
- Supported **supplier quality activities** by reviewing PO compliance, delivery timelines, COA availability, and maintaining supplier performance records.
- Supported **internal quality activities and audit readiness** by maintaining complete and organized QMS records and documentation.

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
- 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 – Quality Management System
- QMS Documentation & Document Control
- SOP & Work Instruction Development
- Audit Documentation & Readiness
- Microsoft Excel

Education

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