KAVITHA REDDY K

Phone: +916361291793 | Email: kavithareddy0310@gmail.com | Location: Bangalore, Karnataka, India

PROFESSIONAL SUMMARY

Results-driven Quality Assurance and Regulatory Affairs Professional with 4+ years of experience in pharmaceutical primary packaging and Class I medical device manufacturing. Expertise in Quality Management Systems (QMS), ISO 13485, ISO 15378, EU MDR 2017/745, CAPA management, validation protocols (IQ/OQ/PQ), and regulatory compliance. Proven ability to lead internal, customer, supplier, and regulatory audits while maintaining audit-ready systems aligned with GMP/GDP and ALCOA++ data integrity principles. Skilled in technical documentation, risk management, root cause analysis, deviation handling, and continuous process improvement within highly regulated manufacturing environments.

KEY SKILLS

• **Quality Assurance & Quality Systems:** QMS, ISO 13485, ISO 15378, EU MDR 2017/745, IMDR 2017, CE Marking, Post-Market Surveillance (PMS), GMP / GDP Compliance

• **Systems & Processes:** CAPA Management, Deviation Handling, Root Cause Analysis (RCA), OOS Investigation, Audit Management

• **Validation & Technical Skills:** Validation (IQ/OQ/PQ), Risk Management - ISO 14971 (EN ISO 14971:2019), Technical Documentation, Validation Documentation, Risk Assessment

• **Audits & Data Integrity:** Internal & External Auditing, Supplier Quality Management, ALCOA++ & Data Integrity

• **Operational Tools:** Kaizen, 5S, Poka-Yoke, MS Word, Excel, PowerPoint

PROFESSIONAL EXPERIENCE

Head - Quality Assurance — Precispharma Containers Private Limited **January 2022 - Present | Bangalore, India**

- Lead Quality Assurance operations for pharmaceutical primary packaging and Class I medical device manufacturing.
- Maintain and improve Quality Management Systems in compliance with ISO 13485, ISO 15378, EU MDR 2017/745, and IMDR 2017 requirements.
- Manage CAPA systems, deviation investigations, root cause analysis, and OOS handling.
- Coordinate and lead customer audits, supplier audits, internal audits, and regulatory inspections.
- Prepare and review technical documentation, CE marking files, Declaration of Conformity, and IFU documentation.
- Execute and monitor validation activities including IQ, OQ, and PQ protocols.
- Conduct risk assessments in accordance with EN ISO 14971:2019 standards.
- Support Post-Market Surveillance (PMS), complaint handling, and mock recall activities.
- Collaborate with cross-functional teams to improve operational efficiency and compliance readiness.

EDUCATION

Master of Science (M.Sc.) - Microbiology — University of Mysore, Manasagangotri Campus

CERTIFICATIONS

• Certified Internal Auditor - EN ISO 13485:2016

• Certified Internal Auditor - ISO 15378:2017

• Trained in EU MDR 2017/745 & IMDR 2017 Compliance

• Internal Audit & Regulatory Compliance Training

• GMP/GDP & ALCOA++ Documentation Practices

LANGUAGES

English, Kannada, Malayalam, Hindi, Tamil, Telugu