KAVITHAREDDY K

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PROFESSIONAL SUMMARY



QARA adept with over 4 years of progressive experience, beginning as a Quality Executive and progressing to Manager - Quality Assurance, with competence in team management, QMS, and cGMP compliance. Expertise in pharmaceutical primary packaging and Class I M medical devices, with complete process knowledge and managing quality management systems as per EN ISO 13485:2016, ISO 15378:2017, IMDR 2017 & EU MDR 2017/745.

KEY SKILLS

- Quality Assurance & QMS: cGMP, GMP/GDP, ISO 13485, ISO 15378
- Medical Devices & Regulatory: Class I M, EU MDR 2017/745, CE Marking, GSPR, IFU, Technical Documentation, Clinical Evaluation, PMS.
- Quality Systems: CAPA, Deviations, OOS, RCA, Change Control, Complaint Management, Non-Conformance Closure.
- Audits: Internal, Customer & Vendor Audits, Audit Management, Observation Closure.
- Vendor Management: Vendor Qualification, Vendor Management, Supplier Evaluation, Vendor Performance Management
- Risk & Validation: EN ISO 14971:2019, Risk Assessment, FMEA, IQ/OQ/PQ, Validation
- Regulatory Coordination: Notified Body Coordination, EUDAMED & CDSCO registration
- Management: Team Management, Cross-Functional Coordination, Continuous Improvement
- Data Integrity: ALCOA++, Data Integrity, GMP Documentation

EXPERIENCE

January 2022 to Present - Precispharma Containers Private Limited, working as Manager, Quality Assurance

- 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, complaint handling, and mock recall activities.
- Collaborate with cross-functional teams to improve operational efficiency and compliance readiness

EDUCATION

2018 – 2020 Master of Science (M.Sc.) - Microbiology
University of Mysore, Manasa Gangotri Campus

2015 – 2018 Bachelor of Science(B.sc) – Biochemistry, Zoology and Microbiology
Maharani Lakshmi Ammanni College for Women, Bangalore University

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CERTIFICATIONS

- Certified Internal Auditor - EN ISO 13485:2016
- Certified Internal Auditor - ISO 15378:2017

LANGUAGES

English, Kannada, Malayalam, Hindi, Tamil, Telugu