ABINAYA M

REGULATORY AFFAIRS ENGINEER



CONTACT

+91 7603847520

abinayamu2003@gmail.com

Bangalore, Karnataka

https://www.linkedin.com/in/abinayamuruganbb7336287/

EDUCATION

B.E - BIOMEDICAL ENGINEERING

VIVEKANANDHA COLLEGE OF ENGINEERING FOR WOMEN

2021 - 2025

CGPA - 9.4

HIGHER SECONDARY CERTIFICATE

VIJAY VIDYALAYA MATRIC HR SEC SCHOOL

2020 - 2021

PERCENTAGE - 95%

CORE COMPETENCIES

- CDSCO Manufacturing Licence Activities – MD-5 and MD-9
- EU MDR 2017/745
- ISO 13485:2016 – Quality Management System
- ISO 14971:2019 – Risk Management
- Change Management (ECR/ECN)
- CAPA and Nonconformity Management
- SOP Development and Review
- Document Control

LANGUAGES

- English
- Tamil
- Kannada (Basic)

PROFESSIONAL SUMMARY

Regulatory Affairs Engineer with experience in medical device manufacturing, supporting regulatory compliance and Quality Management System (QMS) activities for Class IIa, Class B and Class C medical devices. Experienced in CDSCO manufacturing licence activities (MD-5 and MD-9), EU MDR 2017/745 documentation, design change control, risk management documentation, CAPA, internal and surveillance audits, and document control. Knowledge of ISO 13485:2016, ISO 14971:2019, FDA 21 CFR Part 820 (QMSR) and global medical device regulatory requirements, with experience coordinating cross-functional teams to maintain product compliance, documentation traceability and quality system effectiveness.

WORK EXPERIENCE

ENGINEER - REGULATORY AFFAIRS

16JUN 2025 - 01 SEP 2026

ICALTECH INNOVATIONS PVT LTD., Bangalore.

DESIGN CONTROL AND CHANGE MANAGEMENT

- Handled Change Management activities by reviewing Engineering Change Requests (ECRs) and Engineering Change Notices (ECNs), updating controlled documents, and ensuring traceability in accordance with Quality Management System (QMS) requirements.

CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA)

- Coordinated Corrective and Preventive Action (CAPA) documentation by supporting root cause analysis, implementing corrective actions, maintaining CAPA records, and monitoring effectiveness checks.

AUDIT AND REGULATORY SUPPORT

- Supported EU MDR (2017/745) compliance activities by preparing and maintaining regulatory plans, reports, records, and technical documentation.
- Assisted in ISO 13485:2016 Surveillance Audit preparation by reviewing controlled documents, ensuring record completeness, and supporting closure of audit observations.
- Supported the preparation and submission of documentation for CDSCO site change licensing, including preparation of regulatory forms, supporting documents, and records for regulatory submission.
- Supported ZED Bronze Certification by preparing and maintaining quality documentation, SOPs, process records, compliance evidence, and assessment-related documents, ensuring readiness for certification and adherence to Quality Management System requirements.
- Prepared and maintained the Internal Audit Plan, Audit Schedule, and Internal Audit Reports, supporting systematic audit execution, documentation of audit findings, and continuous improvement of the Quality Management System.

CROSS - FUNCTIONAL COLLABORATION

- Coordinated with Research & Development, Quality Assurance, Manufacturing, and Production teams to ensure timely completion of regulatory documentation and compliance activities.

CREDENTIALS

- Completed I**SO 13485 : 2016 for Medical Devices QMS,** Udemy
- Completed **English Typewriting Junior** with First Class Distinction.

PROFESSIONAL QUALIFICATION

Executive Diploma in Regulatory Affairs (Medical Devices) - Institute of Good Manufacturing Practices India (IGMPI)

- Gained knowledge of medical device regulatory frameworks, CDSCO licensing procedures, international regulatory requirements, and Quality Management Systems (QMS).
- Capstone Project: Comparative Study of Medical Device Regulations in the USA, Europe, and India, covering regulatory pathways, device classification, technical documentation, and quality management requirements.

REGULATORY AFFAIRS ENGINEER

02 SEP 2026 - PRESENT

Confident Electronics Pvt Ltd., Bangalore

- Support Quality Management System (QMS) implementation and maintenance in accordance with ISO 13485:2016.
- Assist in CDSCO Class C medical device manufacturing licence application activities in accordance with the Medical Devices Rules, 2017.
- Prepare, compile, and review regulatory documentation required for medical device manufacturing licence applications.
- Support preparation and review of SOPs, work instructions, forms, and records to meet applicable regulatory and QMS requirements.

STANDARDS & REGULATIONS WORKED ON

- ISO 13485:2016 Medical Devices Quality Management System(QMS)
- EU MDR(2017/745)
- ISO 14971:2019 - Application of Risk Management to Medical Devices
- Medical Device Rules, 2017
- IEC 60601 -1, IEC 60601-1-2

KEY ACHIEVEMENTS

- Assisted in the timely closure of CE Marking nonconformities (NCs) through documentation review.
- Supported the closure of CDSCO manufacturing site change license observations.
- Contributed to the timely closure of CAPAs by tracking corrective and preventive actions, maintaining CAPA documentation, and supporting effectiveness verification.

INTERNSHIP AND TRAINING

- June 2024 - Completed an Advanced Level Training Cum Internship program at Medingers Healthcare Solutions, a leading healthcare solutions provider in Erode.
- February 2025 - Completed an Advanced Training in Biomedical Applications at Harvey Biomedical, Bangalore.

DECLARATION

I hereby declare that the information provided in this resume is true and accurate to the best of my knowledge.