



B. Kalyani Harish

Sr. Technical Consultant - Regulatory

17+ years of experience in Quality and Regulatory Submissions of active and non-active Medical devices in various Global markets

PROFESSIONAL EXPERIENCE

- Regulatory Subject Matter Expert in active and non-active medical devices. Expert level global regulatory submissions experience. Worked as project lead on regulatory submissions deliverable to ensure compliant, successful, on-time market clearance/approval.
- Handled multiple product registrations and submissions to regulatory bodies. Also, able to maintain registrations and device listings, support the reporting of departmental metrics, support and backup for other Q&R functions, supports internal/external audits and regulatory inspections
- Advise internal stakeholders (marketing, manufacturing, R&D, etc.) regarding current/pending guidance, regulations, agency/industry initiatives, etc. To ensure regulatory strategy is in alignment with company objectives. Review and approve engineering changes, advertising, promotional items and labelling for regulatory compliance
- Identify potential regulatory approvals risks based on changes in regulations, standards country specific issues or other unique characteristics of the project. Provide signification regulatory strategy development and support

Product Experience

Non-active medical devices (Low, Medium and High Risk products)

Active Medical devices (Low, Medium and High Risk products)

PREVIOUS ROLE

Employer – 1

Company Name – **Skaray Healthcare Global, Bangalore**

Designation – Manager QARA

Product – Patient Monitoring Systems, Respiratory Management Systems, Radiology Systems and Defibrillators

Employer – 2

Company Name – **Opto Circuits India Limited (R&D Division), Bangalore**

Designation – Deputy Manager QARA

Product – Automated External Defibrillators, Vital Sign Patient Monitors, Peripheral Arterial Disease Devices, and Pulse Oximeter sensors

Employer – 3

Company Name - **vTitan Corporation Private Limited, Chennai**

Designation - QMS Coordinator

Product - High Precision Syringe Pump, Accuflow Syringe Pump & Accuflow Large Volume Infusion Pump

EDUCATION

- ❖ Bachelor of Business Management