Sakthivel Balu

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Education

Texas A&M University **Aug 2024 – May 2026**
Master of Engineering, Biomedical Engineering – GPA: 3.63 *College Station, TX*

Anna University **Jun 2019 – May 2023**
Bachelor of Engineering, Biomedical Engineering – GPA: 3.45 *Coimbatore, IN*

Experience

Solenic Medical Inc. **Jun 2025 – Dec 2025**
Quality Engineering Intern *Dallas, TX*

- Supported the Quality Management System (QMS) in compliance with ISO 13485 and FDA 21 CFR 820, ensuring effective document control and regulatory alignment.
- Developed and maintained Design Inputs, Design Outputs, and Verification documentation ensuring traceability between requirements, risks, and verification activities within the eQMS.
- Executed risk management activities including hazard identification, failure analysis, and implementation of risk controls in accordance with ISO 14971.
- Conducted incoming inspection and functional testing of medical and electronic devices following FDA Quality System Regulations and approved test procedures.
- Created and routed Change Orders (COs) for controlled documents and part releases while maintaining configuration control across the Quality System.
- Managed supplier quality documentation supporting supplier qualification, audits, and compliance with purchasing control procedures.
- Streamlined document organization within the eQMS by structuring attributes and document views to improve traceability and cross-functional accessibility.

Trimed Solution **Jun 2023 – Nov 2023**
Clinical Engineering Intern *Hyderabad, IN*

- Supported maintenance, testing, and troubleshooting of ventilators, infusion pumps, and patient monitors contributing to 95% equipment availability in ICU settings.
- Assisted with installation, calibration, and preventive maintenance under senior clinical engineers ensuring full compliance with operational safety protocols.
- Performed functional checks and safety inspections according to hospital procedures and manufacturer guidelines, reducing equipment-related issues by 20%.
- Maintained service documentation with 98% accuracy, supporting effective communication with clinical staff and timely issue resolution.

Projects

Monopolar RF Based Atrial Septostomy System **Aug 2024**

- Engineered a fetal atrial septoplasty device to create a patent opening across the fetal atrial septum for treatment of HLHS, drafting 25+ design specifications aligned with FDA regulations and ISO 14971 risk management standards.
- Built and tested functional prototypes ensuring compliance with FDA and ISO 13485 while documenting activities within the Design History File (DHF), including FMEA and Verification & Validation (V&V).
- Conducted safety analyses, risk assessments, and biocompatibility testing to verify device durability, performance, and patient safety.

Regulatory Compliance and QMS for Medical Devices **Aug 2025**

- Developed CAPAs and PMA documentation for a coronary stent,ensuring compliance with FDA and ISO 13485 standards and implementing strategies to address non-compliance issues.
- Analyzed FDA warning letters on QMS non-compliance and proposed strategies to enhance regulatory adherence.
- Designed nonclinical and clinical plans to ensure device safety,efficacy and compliance,emphasizing patient protection and manufaturing processes.

Technical Skills

Quality & Regulatory: DHF, DFMEA, Risk Assessment, ISO 14971 Risk Management, Process Validation, Quality System Regulation, ISO 13485, FDA 21 CFR 820, Design Verification & Validation
Software: SolidWorks, Microsoft Office (Excel, Word, PowerPoint), Minitab
Product Development: Prototyping, 3D Printing, Good Manufacturing Practices (GMP), Good Laboratory Practice (GLP)