



<https://www.biolinek360.com/job/senior-quality-engineer-software/>

Senior Quality Engineer

Description

Position: Senior Quality Engineer, SaMD

Location: Denver, CO

Reports to: Division VP

Salary Range: 95-140K

This company is leading the next evolution of clinical decision-making and patient workflow. We are seeking an experienced Quality Engineer to lead quality engineering activities. The person in this role will be responsible for ensuring the quality, functionality, and reliability of our SaMD applications through rigorous testing, analysis, and the implementation of quality assurance processes. This role is instrumental to drive continuous improvement efforts through facilitating, leading, and collaborating with cross function teams including quality, engineering, production, clinical, and regulatory affairs.

Responsibilities

- Assist in the implementation, compliance, and maintenance of standards (e.g., FDA, ISO13485) and Quality policies and procedures.
- Perform investigation of product nonconformance/complaints, root cause analysis, monitoring/trending of process and product, and escalation of identified issues
- Devise & implement quality standards for software quality processes, systems, and procedures to support the software life cycle.
- Perform design control and risk management activities by working closely with cross functional teams.
- Ensure product requirements for traceability, risk remediation and testability are met.
- Meet verification and validation deliverables for compliance with regulatory affairs requirements.
- Oversee gap analysis and remediation activities.

Qualifications

- BS or MS/Engineering Degree with 5+ years of experience,
- Previous experience working with Quality Management Systems (QMS), with knowledge of ISO 13485 and 21 CFR 820.
- Experience with IEC 62304.
- 2+ years of experience with SaMD products, preferably in the life science industry.
- DHF and Risk Management experience, to include reporting and remediation

Hiring organization

BioLink 360

Employment Type

Full-time

Job Location

Denver, CO

Date posted

January 16, 2025