Position location: Woburn MA
Industry: Medical Device
Position: Sr Software Quality Engineer
Salary: $85-$105,000
Position type: Permanent Full time Employee
Relocation Assistance: Provided
Not considering visa candidates.

Join a passionate team! This is a great group of people to work with and growing company. Apply today!

In this exciting role as a Sr. Software Quality Engineer, you will serve as a subject matter expert by leading and providing technical design quality support for the new product development and sustaining projects. The individual will act as a subject matter expert and provide guidance to the business in interpreting and executing against Company quality system elements including software/system work products to ensure compliance. This individual will ensure that all system-level project / program work products (e.g., plans, requirements, specifications, tests, test results, traceability, risk management documents, reports) meet Company's quality, reliability, and compliance requirements. This individual will ensure Design Quality Assurance-driven initiatives meet objectives in delivering highest quality products, with supporting tools and processes.

MITG

The Minimally Invasive Therapies Group strives to enable earlier diagnosis, better treatment, faster complication-free recovery, and enhanced patient outcomes through less invasive surgical solutions.

SURGICAL INNOVATIONS sets the standard for Minimally Invasive Surgery (MIS) by creating innovative surgical products and services that focus on obesity and diseases and conditions of the gastrointestinal tract, lung, abdominal wall, pelvic region, and the head and neck.

A Day in the Life

- Leading large and complex medical device product development per the FDA design controls starting from design planning through design transfer.
- Collaborating with project / program teams to ensure work products comply with Company procedures, acceptable qualitative and quantitative criteria, and global standards, regulations, and guidance.

- Working very closely with the development teams during early development of requirements & design (algorithm development and code) and providing feedback to the design based upon SFMEA/Hazard Analysis.
- Ability to read software code and participate in detailed technical design and code reviews.
- Understanding of the interdependencies of program work products and guide the teams in execution strategy and participating in development, review and approval of all program work products (e.g. plans, requirements, specifications, tests, test results, traceability, risk management documents, reports).

- Generating and driving risk management deliverables like SFMEA and Hazard Analysis and preferably experienced in facilitation / execution of the SFMEAs.
- Chair cross-functional change control boards.
- Utilizes knowledge of various Software Development Lifecycles (SDLC).
- Training and coaching cross-functional peers on maintaining compliance to internal and external Quality requirements and regulations in support of the deployment of the different BU strategies and products.
- Driving clarity and consistency in documentation.
- Leading CAPA projects and assisting post market analysis.
- Participating in support of external regulatory audits and inspections.
- Driving Process improvement activities.
- Work under consultative direction toward predetermined long-range goals and objectives. Assignments are often self-initiated. Determine and pursue courses of action necessary to obtain desired results through consultation and agreement with others rather than by formal review of superior.
- Performs other related duties as assigned.

Must Have: Minimum Requirements

- Bachelor's Degree in Engineering or Science with 4+ years of work experience in Quality and/or Software Development
- OR Advanced Degree in Engineering or Science with 2+ years of work experience in Quality and/or Software Development.
- Experience working in a regulated industry (e.g., FDA-regulated).

Nice to Have (Preferred Qualifications)

- Master's Degree in Engineering, Quality, Regulatory, or related.
- Working knowledge of embedded and mobile application development for medical devices.
- Working knowledge of ISO 13485, ISO 14971, 21 CFR 820, IEC 62304, IEC 60601-1 and MDD.
- Ability to author technical reports, business correspondence and standard operating procedures.
- Ability to apply knowledge and work with development and supply vendors to ensure compliance to Company requirements.
- Strong verbal and written English communication skills with an ability to effectively communicate at multiple hierarchal levels in the organization.
- Ability to multi-tasks, prioritize, meets/exceed deadlines and hold themselves, and others accountable.
- Self-Starter with a sharp focus on quality and customer experience.

Excellent growth opportunities.

PLEASE CHECK YOUR EMAIL / A RESPONSE TO YOUR APPLICATION WILL TYPICALLY ARRIVE VIA EMAIL WITHIN 24 HOURS.** ***Please also check SPAM. ** Also, the system can only accept resumes in PDF or WORD format.