



Software Quality Engineer

Job Description

Intelon Optics is a rapidly-expanding world class technology and innovation company.

This position offers the opportunity to contribute to the Medical Technology business and help shape the future of intelligent medical devices for ophthalmology. If you are excited about solving complex, multivariate technical and systems challenges in the medical domain, are passionate about developing safe, robust and compliant high quality medical device that serves a meaningful purpose, and have excellent interpersonal and leadership skills, then this role could be for you. You will work with R&D team and lead the creation of innovative optical products and technologies. Your primary role would be to provide Software Quality Assurance testing and ensure compliance in the support of medical device development life cycles.

In this fast-paced startup environment you will need excellent interpersonal skills, keen attention to detail, excellent communication/documentation, and ability to collaboratively and responsively, focusing on key priorities based on new information and product development timeline. You should have high energy and excitement to contribute to cutting-edge technology that improves medical care.

This role is based in our new state-of-the-art innovation center, located in Lexington, MA.

Responsibilities

- Perform and Review all test methods, design verification and validations on complex opto-electro-mechanical medical system with software controls. Work with R&D team to establish and document product requirements, test protocols and generate test reports.
- Create and maintain requirements trace matrix.
- Review Design and Development paperwork, records, etc. for compliance to internal procedures and regulations. Participate in Phase/Design Reviews.
- Collaborate with engineers and SMEs to direct device risk management activities including UFMEA, DFMEA, PFMEA.
- Verify data integrity, electronic data storage and data sheet validations.
- Perform Data/Statistical analysis as needed. Support scientific, complaint, and test failure investigations.
- Providing support during internal and external audits

Requirements

BS in Engineering or related field and 4+ years or MS and 2+ year experience in medical device industry, particularly in medical equipment (software and hardware combination devices).

We are looking for someone who is adaptable, self-motivated, and able to work under pressure. We will expect you to be able to work collaboratively as part of a team and have the strong initiative and drive to work independently. You should have excellent interpersonal, communication, and presentation skills. Demonstrable track record of getting medical products through regulatory approvals is a significant plus.

Minimum Qualification

- Excellent communication skills
- Strong understanding of Design Control process in Medical Device industry.
- A good understanding of the development principles applicable to regulated products
- Technical training and experience using Statistics, Lean and Six Sigma Methodologies (i.e. including Measurement System Analysis, SPC, DOEs, Reliability, etc.)
- Knowledge of statistical software packages is preferred with the ability to preview, graph and analyze data

Preferred Additional Qualifications

- Ability to read and understand technical documentation in a form of Visio diagrams, flowcharts, UML diagrams is a plus
- Knowledge and ability to use application control and performance evaluation tools (Services, Device Manager, Task manager, etc.)
- Attention to details, experience with instrument control software specifics
- Understanding and experience with Agile product development workflow and practices
- Practical experience with JIRA required, other workflow / document collaboration tools (Confluence) is a plus
- Technical background in software or other engineering discipline
- Understanding US and International regulations and guidances for Medical Devices
- Experience working with both an FDA and European regulatory agencies
- Previous project management and/or project leadership experience

Benefits

Competitive salary and benefits with company incentive plan.

As part of our dedication to the diversity of our staff, Intelon Optics, Inc. is committed to Equal Employment Opportunity without regard for race, color, national origin, ethnicity, gender, protected veteran status, disability, sexual orientation, gender identity, or religion.

To Apply

Please email team@intelon.com with your resume and a cover letter attached.