## Senior Quality Engineer

### The Company:

NinePoint Medical is a fast-paced medical device start-up based out of Bedford MA. With our recent strategic investment from Merit Medical, we are expanding our product development team. We develop, manufacture and commercialize cutting-edge medical imaging products with a big vision to detect, diagnose, and treat cancer before it becomes cancer. Today's standard of care for diagnosis of disease relies on obtaining a tissue sample and performing costly processing and expert review of tissue sections. Using breakthrough optical imaging technology along with advanced machine learning algorithms, NinePoint Medical will provide treating physicians with real-time diagnostic capability, thus streamlining patient care, reducing cost, and improving outcomes. The research and development team is composed of a small but diverse group of talented electrical, mechanical, optical, imaging, software and quality engineers who strive to make a direct impact on patients' lives every day.

### Position Requirements:

We are seeking a talented Senior Quality Engineer to provide quality assurance support of medical device products, with an emphasis on design and development activities. This individual will facilitate the application of design controls, risk management and usability for complex electromechanical medical devices that include software and sterile, single-use disposables. The right candidate will have a succesful track record of hands-on experience with the development and implementation of processes to design, assess, and monitor new and sustaining product development. In addition, this individual will help develop, establish and maintain quality methodologies, systems, practices to product design and operations related functions to meet corporate requirements.

## Key Responsibilities:

- Provide design assurance support and leadership in the design and development of medical device products
- Key developer, advisor and reviewer of validation methods and protocols, test methods, statistical analysis, and specification derivation and assignment.
- Key contributor to design verification and validation plans.
- Implement all NinePoint product design control and risk management activities.
- Establish, communicate, and control risks for risk management reporting.
- Ensure that product development projects and changes to existing products are conducted in compliance with the FDA Quality System Regulation, ISO 13485 and Medical Device Directives.
- Provide Quality Systems support throughout the organization, including operational, customer feedback and document control

**Required Experience:**

- 5-10 years of quality related experience within the medical device industry
- Working knowledge of ISO13485, Medical Device Directive and QSR requirements
- Working knowledge of risk management standard ISO 14971. Experience in working with hazard analyses and risk analysis tools, such as FMEA, and FTA.
- Knowledge of Quality Engineering methodologies such as Design and Process Validation, Risk Management, Quality Systems, Continuous Improvement, and Corrective and Preventive Action
- Proven track record with the creation of plans, procedures, reports and processes
- Knowledge of customer complaints, CAPA, audits processes
- Knowledge of Manufacturing Engineering or Manufacturing Quality Engineering
- Experience in Problem-Solving and developing Quality Policies and Procedures
- Proficiency with Microsoft Office (Word and Excel required), Powerpoint, Access experience
- Strong written/verbal communication skills and demonstrated use of Quality tools/ methodologies.
- ASQ certification (CQE, CQA) a plus
- Working knowledge of software design control standards and related guidance's such as IEC62304 preferred
- Knowledge of electrical and laser safety standards such as IEC60601-1 and its corollaries, as well as IEC60825-1 and 21 CFR 1040 preferred

**Education/General Requirements:**

- A Bachelor's Degree in a Science/Engineering or other relevant technical discipline with 5-10 years of experience working in design quality engineering, preferably at an electromechanical medical device design/manufacturer.
- Strong customer focus, highly organized, responsible and detail oriented
- Excellent written and verbal communication skills - must be able to write clear plans, procedure, and reports

## The Nine Points for Success

1. **Excellence**: constantly create high quality products that improve patient care
2. **Quality**: be better than industry standard in the quality of our people and the efficiency of our operations
3. **Accountability**: Cultivate individual responsibility and promote personal and professional growth
4. **Innovation**: value high quality innovation
5. **Commitment**: create and maintain a positive work environment that is fun and rewarding to be a part of
6. **Teamwork**: value relationships that build respect and foster team work
7. **Communication**: utilize good communication
8. **Empowerment**: make a difference
9. **Diversity**: value diversity of people and opinion