



Director, Catheter and Mechanical Engineering

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 and software engineers who strive to make a direct impact on patients' lives every day.

Position Requirements:

This is an exciting opportunity to join NinePoint and work on the development and commercialization of state-of-the-art medical imaging devices. We are seeking a motivated and hands on individual to direct, oversee and manage our catheter device and mechanical engineering teams. This position will be responsible for leading the design through commercialization of single-use catheter devices incorporating NinePoint Medical's advanced imaging technology. In addition, this position will also own and oversee the mechanical engineering activities, with specific focus on our next generation imaging instrumentation. The qualified candidate will need to lead a cross-functional team through concept, design and development and will report directly to the Vice President of Research and Development. This is a critical and challenging position with many moving parts requiring strong technical and managerial skills.

Key Responsibilities:

- Inspire, rally and lead the Catheter Device and Mechanical Engineering team
- Participate in brainstorming, prototyping and analysis of next generation catheter device and electro-opto-mechanical concepts and designs, help form future roadmap
- Work alongside talented electrical, mechanical, optical and imaging engineers to develop innovative solutions to real world medical problems, push the status quo
- Engineer solutions using proven and innovative manufacturing techniques
- Participate in risk management activities across product portfolio
- Decompose projects into discrete tasks and work with management to effectively resource, schedule and provide status updates
- Formulate and support the required preclinical testing to prove safety and efficacy
- Mentor and supervise engineers

Required Experience:

- 10+ years of relevant experience in the design and commercialization of catheter/disposable devices
- 5+ years' experience with direct reports
- Project management, risk assessment and resource planning
- Experience determining the clinical user needs and gaining feedback directly from the practicing physicians
- Experience working in a regulated industry, specifically under FDA QSR, UL/IEC 60601 and ISO 13485 design control requirements

Desirable Experience:

- Endoscopic or vascular catheter experience
- Strong understanding of plastics used in medical applications
- Plastic processing: balloon forming, injection molding, extrusion
- Catheter bonding operations (thermal, adhesive)
- Solid understanding of statistics for both design and process applications
- Process automation as related to catheter manufacturing
- Mechanical engineering of medical instrumentation
- Robotics and motion control systems

Education/General Requirements:

- A minimum of a technical Bachelors or equivalent required. Masters Degree desirable.
- Preferred fields: Biomedical engineering, Plastics engineering, Mechanical engineering, Chemical engineering
- Strong customer focus, highly organized, responsible and detail oriented
- Excellent written and verbal communication skills - must be able to write clear reports, specifications, proposals and effectively discuss them with other members of a multi-disciplinary team (R&D, MFG, Quality, Clinical, Marketing, Sales)
- Clear understanding of the role of engineering in a manufacturing environment and proven track record of transferring designs into manufacturing
- Exposure to reliability engineering

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