



**Position:** Senior Manufacturing Engineer  
**Department:** Manufacturing Engineering  
**Reports to:** Manufacturing Engineering Manager  
**Location:** Columbia, SC

### **Job Description**

The Senior Manufacturing Engineer is responsible for the development, optimization, and validation of processes and systems to support the manufacturing scale up of our medical device, Simplicity.

### **Key Responsibilities & Essential Functions**

#### **Using engineering skills to:**

- Work within final assembly manufacturing environment(s) and drive early-stage process development and manufacturing optimization to ensure products meet design intent.
- Work with and manage external suppliers, conduct DFM reviews, and go onsite as needed.
- Develop and implement manufacturing processes and measurement methods to meet tight tolerance manufacturing requirements and manufacturing scale up.
- Lead development of fixtures, equipment, and automation.
- Interface with contract manufacturers and suppliers.
- Process evaluations and lead process optimization initiatives utilizing tools such as SPC, DOE, PFMEA, and MSA.
- Evaluation and continuous improvement of process capabilities.
- Develop and lead projects to improve process monitoring, quality and reduce costs.
- Conduct root cause failure analysis and corrective action.
- Establish sampling and Quality plans
- Participate and/or lead risk management activities including product and process FMEA.
- Support reliability engineering activities.
- Participate and/or lead validation activities for design, process, or products.
- Development and qualification of test methods for verifications and validations.
- Write and execute study protocols, technical reports, manufacturing work instructions (MWI), validations, reports, batch records, design control and other documents as required.
- Participate on project teams or leading internal teams. Communicate activities across the organization. Interface with various departments to ensure processes and designs are compatible with the manufacturing environment, launch strategy, and CeQur's objectives.
- Partners with Quality and Regulatory, R&D, and operations to ensure compliance of the manufacturing processes, provide support, for regulatory filings, and ensure the robustness of the process and raw materials.



## **Job Specifications: Background and Qualification Requirements**

- Proven ability to solve problems and improve manufacturing processes that use high precision mechanical components.
- Experience in the scale-up of high volume consumable medical devices.
- Strong working knowledge and experience in manufacturing processes, process development and validations for finished medical devices.
- Knowledge of laser welding, heat staking, engraving and plastics processing equipment a plus.
- Successful implementation and use of statistical based quality improvement tools such as design of experiments, Statistical Process Control and GAGE R&R.
- Experience in equipment and automation development
- Knowledge of medical regulations; ISO13485 and CGMP procedures.
- Project leadership in multi-disciplined projects.
- Experienced in quality system requirements for the medical device industry.
- Proven ability to motivate and lead others, often without direct control, such as suppliers.
- Self-motivated, team-oriented individual who collaborates and communicates effectively with local and international team members in a cross-functional, multi-cultural, interdisciplinary environment.
- Comfortable working in an extremely dynamic and fast paced environment, and able to meet aggressive development milestones.
- Strong verbal and written communication skills.

## **Education and Experience**

- A BS in Mechanical, Manufacturing, or related Engineering field is required, MS preferred.
- Minimum of 4 years of medical device design and development experience, preferably on class II or III medical devices.
- Experience in high volume product design ( >10 million units per year), a strong plus
- A Track record of generating novel ideas, and out of the box thinker and a true entrepreneurial mind set, a strong plus.
- Up to 50% travel required.

This description reflects management's assignment of essential functions; it does not proscribe or restrict the tasks that may be assigned.

Compensation will be commensurate with experience and skills.

Please send resume to [careers@cequr.com](mailto:careers@cequr.com).