Position: Manufacturing Engineer
Department: Manufacturing Engineering
Reports to: VP of Operations
Location: Columbia, SC

Job Description

The 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:

- 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.
- 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

- Capability to solve problems and improve manufacturing processes that use high precision mechanical components.
- Working knowledge in manufacturing processes, process development and validations for finished medical devices preferred.
- Understanding of 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.
- Basic Project leadership fundamentals.
- Basic Understanding in quality system requirements for the medical device industry.
- Proven ability to motivate and lead others, often with limited 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 a realistic development milestones.
- Strong verbal and written communication skills.

Education and Experience

- A BS in Mechanical, Manufacturing, or related Engineering field is required.
- Minimum of two years' experience in manufacturing and/or engineering.

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.