Job Title: Senior Manufacturing Engineer

Department: Operations

Reports To: Manufacturing Engineering Manager

Location: Columbia, South Carolina

CeQur® Corporation develops and commercializes a discrete, simple-to-use and wearable insulin delivery device that easily integrates into patients' daily lives. CeQur Simplicity™ is a 3 Day Insulin Patch designed to reduce the barriers and challenges of multiple daily injections to enable people with diabetes to achieve glycemic targets. CeQur Simplicity™ is FDA cleared and CE marked.

At CeQur, we aim to provide solutions to people with diabetes that are profoundly simple and clinically effective. We are gaining tremendous momentum already, recently closed a very significant series C5 round of $115M, and have built a leadership team and board that comprises of accomplished and respected industry experts. We are looking for like-minded A+ team players to join our team to help make a difference and build a legacy while driving penetration of our therapies. CeQur values a collaborative and creative mindset, where each team member is encouraged to contribute to our processes, decisions, planning and company culture.

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:

- 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.

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