Quality Engineer

Under the direct supervision of the Vice President of Quality, the *Quality Engineer* works with cross functional teams to execute direction for the company's Quality compliance requirements on new and existing devices. This position is responsible for the day-to-day execution of all Quality System requirements to stay ISO/QSR compliant.

ESSENTIAL RESPONSIBILITIES/FUNCTIONS:

To perform this job successfully, an individual must be able to perform each essential function satisfactorily:

* Support the development of the Company's quality objectives and work with the company employees to ensure ISO/QSR compliance.
* Participate in regulatory and quality audits as required to maintain ISO/QSR compliance.
* Collaborate with internal and external partners e.g., laboratories, manufacturers, and packagers, to provide medical devices that meet quality requirements for new and existing products.
* Work with product development and operations to design and produce labeling, work instructions, test methods, and instructional and promotional materials that comply with quality requirements.
* Perform administrative activities associated with the department. This will include DHR review, NCR and CAPA generation, processing, creation of quality records, risk assessment, ownership of all document control workflows, and support Management Review.
* Analyzes process non-conformances and implements comprehensive corrective and preventive action plans.
* Support the quality system maintenance per all applicable medical device regulations, including QSR, ISO13485, MDSAP, and other standards.
* Medcura is a startup entrepreneurial environment, and each employee may be asked to assist in work in areas outside of their usual duties.

EDUCATION AND EXPERIENCE:

- Four-year degree in engineering or related technical degree. Minimum four years of relevant work experience in the medical device field or related industry.
- Demonstrates competencies and ability to support Medcura corporate objectives.
- Experience in process improvement engineering or product/process improvement areas is preferred.
- Experience in Quality function or responsibility for ownership of quality system elements within the role(s) is preferred.
- Working knowledge and understanding of QSR, ISO (13485), FDA and EU MDR and other medical device industry quality requirements. Must be able to understand and apply regulated principles in work experience.
- American Society of Quality (ASQ) certification (CSQE, CQE, CQA, etc.) is a plus/preferred.
- Ability to follow instructions in performing repetitive tasks. Attentiveness in performing tasks.
- Ability to work as a team member in manufacturing and quality custom polymer based gels.

SKILLS & ABILITIES

The ideal candidate will possess the following qualifications:

- Excellent verbal and written communication skills.
- Collaborative individual with strong people skills, management, and leadership skills
- Strong leadership, excellent organizational skills, and a good blend of discipline and creativity.
- Solid analytical skills and the ability to solve problems quickly.
- Knowledge of chemical processing and batch production.
- Commitment to Medcura with the ability to function within a start-up environment.
- Skilled in Microsoft Office (Word, Excel, PowerPoint, and Outlook).
- Understanding of FDA requirements and ISO 13485.