Regulatory Affairs/Quality Assurance Specialist

Under the supervision of the SVP of Regulatory and Clinical Affairs, the *RA/QA Specialist* works with cross-functional teams to support documentation and Quality compliance requirements on new and existing devices, as well as writing to support US and OUS regulatory submissions. This position supports product and operational compliance related to Class-3 medical device design and manufacture, obtaining regulatory approvals, and establishing and maintaining quality control and assurance in keeping with business objectives. The Regulatory Affairs and Quality Assurance Specialist oversees or participates in external regulatory inspections and ensures the timely filing of documents, records, and reports with various regulatory agencies. The position manages quality assurance and regulatory affairs activities per the approved budget and annual operating plan.

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 and regulatory objectives and work with the company employees to support medical device development and regulatory approvals.
- Creation and completion of design history file documentation for multiple medical devices. Support risk assessment, regulatory submission, and quality assurance activities.
- Design History File and Device Master File support.
- 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.
- Develop and manage quality and regulatory-related deliverables during product development, including risk files, verification, and validation documentation, DMFs, and regulatory submissions.
- Drive the quality of manufactured products including development of written quality plans for products; identification of key component attributes for inspection and/or process control; driving supplier quality through qualifications and audits; support the development of device history records and device master records; supporting CAPA and continuous quality improvements in manufacturing.
- Support global product registrations of medical devices by providing technical documentation from the technical product file and answering questions from regulatory bodies assessing the safety and efficacy of the product.
- Actively comply with Medcura's Quality System.
- 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. A minimum of 5 years of relevant work experience in the medical device field.
- Design control experience in a regulated environment.
- Working knowledge of medical device regulations for FDA, EU MDR, ISO 13485.

- Ability to work as a team member in the development of custom polymer based medical devices.

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.
- Ability to collaborate effectively with a team and individually.
- Strong leadership, excellent organizational skills, and a good blend of discipline and creativity.
- Solid analytical skills and the ability to problem-solve quickly.
- Knowledge of medical devices and regulatory requirements.
- Commitment to the company with the ability to function within a start-up environment.
- Skilled in Microsoft Office (Word, Excel, PowerPoint, and Outlook).
- Understanding of FDA, EU MDR, and ISO 13485 requirements.