Position Description:
Quality & Regulatory Manager/Director

Intelivation Technologies is a medical device company focused on spine, extremities, and sports medicine. We design, develop, and commercialize state of the art implants and instruments that aim to provide clinical benefit to patients. This position will be working in a highly fast paced start-up styled environment where everyone wears multiple hats, and the candidate needs to be a hands-on person who can pitch in wherever needed.

The Quality & Regulatory Manager/Director will lead the process of achieving high quality standards for the company, while maintaining and improving our Quality Management System. This individual will be responsible for ensuring compliance with all US FDA regulations and will lead the company in its ISO 13485 certification.

Responsibilities:

- Develop and maintain QSR compliant processes which control the quality of parts and product throughout the procurement and production cycle.
- Support the design and development of new or improved products in close collaboration with Product Development, Project Management, Marketing etc.
- Lead and support the execution of all Risk Management and Risk Analysis activities, FMEAs and control plans.
- Develop Reliability models for predicting product performance over time.
- Develop statistically based sampling plans for Design Verification and Validation, Process Validation, or other studies as deemed necessary.
- Participate in FDA inspections, ISO Certification and surveillance audits and customer audits as a subject matter expert.
- Writing & coordinating efforts for the development and implementation of new and updated Quality System procedures for ISO/QSR, such as validation protocols, product & material specifications, design & development documentation, and SOPs.
- Ensure that all projects are in compliance with GMP, QSR, ISO or other applicable requirements.
- Identify and implement opportunities for continuous improvement in the Quality System.
- Maintain the company's medical device listing and device & tissue establishment registrations.
- Author/prepare regulatory 510K submissions to the FDA, provide additional information request responses, and renewals
- Participate in project teams to develop regulatory strategies, testing requirements, and other documentation to ensure that regulatory submissions meet the company's product launch timelines in all identified markets.
- Interact and coordinate activities with other departments, external vendors, and customers.
- Perform other Quality Systems & Regulatory related duties as required.

Qualifications:

To qualify for this role, you must possess the following:

- Bachelor’s degree with a major in Science or Engineering preferred. Experience in the Medical Device industry is preferred. Masters preferred
- Minimum 3-5 years of progressive work experience in quality assurance with a background in quality engineering, process quality, statistical quality control, and risk management.
- Working knowledge of the 510K submission process.
- Strong knowledge of FDA 21 CFR 820 and ISO 13485 regulations.
- Experience with GTPs is a plus.
- Experience with FDA and ISO Audits
- Experience with the ISO 13485 certification process
- Experience with MS Office and statistical analysis tools
- ASQ certifications preferred.

Location:

This position will be based in Plymouth Meeting, PA

Intelivation Technologies is an Equal Opportunity Employer.