Job Description

Job title: Senior Quality Systems Engineer

Department: Quality and Regulatory Affairs

Reports to: CTO

☒ **Full-time** ☐ **Part-time**	☒ **Exempt** ☐ **Nonexempt**

Essential Duties and Responsibilities:
The Senior Quality Engineer is responsible for implementing, maintaining, and improving Bright Uro's (BU's) Quality Management System (QMS) and providing design assurance expertise during product development and transfer to manufacturing. This individual will collaborate with key internal/external stakeholders and will provide sound approaches to implementing electronic Quality Management System (eQMS) requirements to ensure compliance in a highly efficient manner. The Senior Quality Engineer will also serve as the Subject Matter Expert (SME) for BU's eQMS.

Job Details:

- Implement and improve the QMS in accordance with applicable regulations for a global medical device company. Establish Standard Operating Procedures (SOPs) to align with FDA QSR and ISO 13485:2016 requirements.
- Key member of the product development team representing the Quality function in Design Assurance. Steer and support the design control aspects of product quality, program management, and quality planning from product design through manufacturing.
- Lead supplier quality initiatives to ensure product suppliers are effectively developed, maintained, and monitored. Initiate new supplier relationships and drive opportunities with existing suppliers including support for IQ/OQ/PQ development to ensure robust product design.
- Manage and coordinate Risk Management activities. Lead the development of Risk Management documentation and facilitates updates to Risk Management files.
- Develop processes to investigate manufacturing product quality and compliance issues (i.e. CAPA, NCMR, etc.).
- Oversees Internal Audits to assess compliance to applicable FDA QSR, ISO 13485, and internal standards. Assist with external Audits from Regulatory Agencies (i.e. Notified Bodies, FDA, etc.)
- Review and approve design/development test, design verification, and design validation protocols and reports
- Perform other job-related duties as assigned

Education and/or Work Experience Requirements:

- Minimum of a Bachelors Degree in Science or Engineering. Biomedical Engineering background strongly preferred. Graduate degree preferred but not required.
- 7+ years of Quality Systems and/or Quality Engineering experience in a medical device company (startup experience preferred)
- Expertise in Design Control of Medical Devices and familiarities with associated standards
- Must be able to work independently leading Quality efforts.
- Extensive experience with FDA, ISO 13485, EU MDR, and multi-country QMS requirements
- Hands-on experience with an eQMS (i.e., Greenlight Guru, Master Control, Team Center, Qualio, Aligned Elements, etc.)
- Demonstrated ability to use process development tools (e.g., Lean Six Sigma)
- Demonstrated ability to apply a practical level of statistics to Quality Control processes (e.g., manufacturing)
- Demonstrated ability to communicate and interact with all levels of the organization including Executive Leadership Team (ELT)
- Strong proofreading and writing skills, as well as exemplary attention to detail
- Demonstrated organizational and prioritization skills
- Exceptional decision-making including the ability to rapidly understand complex changes and pace work completion to the needs of the company
- Strong computer knowledge (Expert Level MS Office and Adobe Acrobat), technical writing skills and proofreading ability
- Demonstrated ability to work effectively with cross-functional teams for problem-solving, product, and process improvement is required

Other Requirements:

- High level of personal/professional integrity and trustworthiness with strong work ethic and the ability to work independently
- Proven technical ability with a strong results orientation, positive "can do" attitude and a sense of urgency to get things done
- Strong self-organization and documentation skills

Print Employee Name:
Employee Signature/Date:
Manager Signature/Date: