Senior Quality Engineer

Company Overview:

Prytime Medical Devices, Inc. (The REBOA Company™) is an innovative medical device company that designs, develops, and commercializes minimally invasive solutions for hemorrhage control. Our flagship product is the ER-REBOA™ Catheter. The recent commercialization of this device has created an overwhelming interest in the marketplace. As such, Prytime Medical is seeking an experienced Senior Quality Engineer to assist in the expansion of this market.

Job Summary:

The Senior Quality Engineer will be based in either the San Antonio or Denver office or be willing to relocate to one location. The individual who will thrive in this position is a self-motivated, proficient quality engineer who enjoys the fast pace and accountability of a small company and wants to be a part of a team that takes high value ideas from concept to commercialization. Duties will include, and not be limited to, the following:

- Provide leadership in design and implementation of quality engineering to support entire product life cycle with focus on quality engineering activities such as reliability, risk management, analytics/statistical techniques, requirements management, verification and validation, and design control across the lifecycle of the product.
- Create, execute and sustain Quality Management Systems activities to ensure conformance to ISO, FDA (Food and Drug Administration) and MDD (Medical Devices Directive) requirements.
- Direct development and consistent application of quality policies and procedures in product design and development, ongoing manufacturing and active product lines.
- Conduct NC, RMA and Complaint investigations and root cause analyses.
- Implement and conduct corrective and preventive actions (CAPA), including verifications of effectiveness.
- Act as technical liaison, as needed, between product development, manufacturing, external manufacturers and suppliers.
- Work collaboratively and cohesively with other departments to provide training and guidance on product quality, quality processes and regulatory compliance.
- Execute internal audits against systems and procedures.
- Interact with government and auditing body agencies (FDA, notified bodies) during audits.
- Select, qualify and manage suppliers as a part of the supplier quality system.
- Travel up to 50% time between the Texas and Colorado offices.

Primary Skills and Job Requirements:

- BS or MS in engineering.
- 5-7+ years' experience in medical devices with direct experience in QA/QE environment.
- Excellent working knowledge of Quality Management Systems including document control, training, internal audit, design control, risk management, complaint, CAPA and non-conforming product systems.
- Demonstrated ability to understand and communicate relevant GMP, FDA and ISO regulations (i.e. ISO 13485) to multiple functional areas.
- Strong quality engineering skills with a proven track record in all aspects of the design control process, including functional/design requirements, design verification/validation, and product risk management is required. Root cause analysis skills/experience is required.
- Confident selecting, evaluating and qualifying suppliers of regulated product. Experience in on-site quality audit as lead auditor.
- Experience acting as audit lead for internal and external audits (i.e. Notified Body and FDA.)

- Comfortable establishing and implementing metrics for assessing the suitability and effectiveness of the Quality System including identification and implementation of continuous improvement methods.
- Excellent ability to multi-task between projects.
- Demonstrated ability to prioritize, initiate, and drive projects to completion.
- Excellent interpersonal/communication and technical writing skills.
- Confident taking initiative and ownership of decisions and tasks.
- Thrives in small team environments.

Secondary Skills and Job Requirements:

- Strong experience utilizing Design of Experiments and statistical techniques/software (i.e. JMP, Minitab).
- Knowledge of basic human anatomy.
- Knowledge of clinical settings such as in vivo labs and hospital operating rooms.