QUALITY ENGINEER I / QUALITY ASSURANCE SPECIALIST

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. Prytime Medical's technical office, based in Lakewood, CO, is seeking a Quality Assurance Specialist to add to our team of positive, energetic, and collaborative engineers and technicians. The individual who will thrive in this position is a self-motivated critical thinker 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.

Job Summary:

This position will report to the Quality & Regulatory Manager and be responsible for the following:

- Maintaining, executing and monitoring Quality Management System documentation, records and training.
- Assisting in the development of standard operating procedures, work instructions, and administrative documents.
- Executing and supporting Quality Management Systems activities to maintain ISO 13485 certification.
- Working collaboratively and cohesively with other departments to provide training and guidance on product quality, quality processes and regulatory compliance.
- Maintaining quality and compliance aspects of existing distributed product lines, including product release, post-market activities and regulatory support.
- Interacting with other parts of the organization to provide and maintain key performance indicators and quality metrics.
- Evaluating, implementing and tracking corrective and preventive action plans and quality system improvements.
- Investigating returned materials in wet lab setting, including identification of potential root causes for returns.
- Managing suppliers as a part of the supplier quality system.

Job Requirements:

- BS in Engineering, Physics, Biology or similar with 0-2+ years of experience in medical device or pharmaceutical field (or 10+ years relevant industry experience)
- Excellent organizational skills and ability to multi-task between projects
- Demonstrated ability to prioritize, initiate, and drive projects to completion
- Strong problem solving, analytical thinking and risk assessment abilities
- Excellent interpersonal/communication and technical writing skills
- Thrives in small team environments
- Strong MS Office skills (Word, Excel, PowerPoint)

Desired Skills and Experience:

- Familiarity with Document Control and Training software programs.
- Knowledge of basic human anatomy.
- Comfort in pre-clinical settings such as in vivo labs.
- Ability to travel up to ~10%, when necessary