POTRERO MEDICAL

Position Title: Quality Engineer
Department: QA

Company Overview

Potrero Medical, Inc. is a San Francisco based start-up company developing the next-generation of critical care monitoring tools. Our first product, the Accuryn Monitoring System with Accuryn Sensing Urinary Catheter has already gained 510(k) clearance and is available for sale in the US. This novel urine drainage catheter provides precision data (temperature, urine output, IAP) to guide precision interventions in the hospital ICU and beyond.

Job Description

The Quality Engineer will be responsible for providing engineering support to processes including, but not limited to, Design Control, Design Change, Verification and Validation, Incoming Quality Control, Manufacturing, Supplier Quality and all areas of the Quality Management System. Participates in cross-functional teams to find compliant solutions. Works in conformance with Company procedures.

General Roles and Responsibilities

- Interface with outside suppliers and internal customers in regards to quality issues.
- As a member of the quality assurance staff, participate in the development and review of product and process requirements.
- Monitor and apply standards maintained by external bodies and integrate those within Design, Operations, and Quality System processes.
- Analyze quality data and compile company quality metrics for Management Review.
- Develop and establish quality plans and test plans to ensure products and processes meet defined specifications.
- Interface with outside suppliers and internal customers in regards to quality issues.
- Maintain and work to Company procedures. Ensure that procedures are adequate for quality functions to conform to business and Quality System requirements.
- Investigate complaint and non-conforming material and recommend corrective action plans.
- Contribute to design and manufacturing validation and verification test protocols and reports.
- Support internal and external audits and inspections. Conduct internal audits, as necessary.
- Support the CAPA, NCMR, Supplier Quality and Complaint Handling systems.
- Manage vendor qualification and vendor audits.
- Support the QA Director in improving awareness of quality issues across all departments.
- Performs other duties, as assigned.

Education Requirements: Bachelor's degree is required. ASQ CQE highly desirable.

Experience Requirements: 1-4 years medical device industry experience is necessary and would preferably include both disposable and capital equipment. Experience in working with Class II devices required.

Other Qualifications:

- Excellent interpersonal written and verbal communication skills.
- Knowledge of and experience in manufacturing medical devices in conformance with Quality System Regulation and ISO 13485 requirements.
- Knowledge of analytical tools and methods, including statistics, DOE, and the use of computer/software packages related to design, development, and manufacturing.
- Must have the competence and experience to make decisions affecting Risk Management and product knowledge as required by ISO 14971.

Please provide a resume and cover letter to Eric Lang at elang@potreromed.com