POTRERO MEDICAL

Position Title: Director, QA
Reports to: COO
Department: Quality

Please provide a resume and cover letter to
Devyani Nanduri at dnanduri@potreromed.com

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 Director of Quality Assurance manages the quality department and is responsible for leading the development, implementation and improvement of the department and the company's Quality Management System.

General Roles and Responsibilities

- Actively participate in the preparation and analysis of tactical operating plans and new portfolio plan for manufacturing.
- Apply engineering knowledge to the manufacturing of new products as well as process changes and enhancements
- Represent Quality on product development teams to ensure adherence to company quality procedures and applicable US and OUS regulatory requirements
- Be the Quality and medical device Design Control and Quality Engineering subject matter experts
- Be the Quality lead on product development teams in matters relating to Quality Engineering and Design Controls
- Support Design Control activities for new products, including effective and efficient use of Quality Engineering techniques such as risk analysis in accordance with ISO 14971, device software development in accordance with IEC62304, test method development, statistical data analysis and the development of sampling plans.
- Lead the development of comprehensive risk management plans and activities (Hazard Analysis, FTA, FMEA, etc.) for the product, ensuing critical design information is translated to the manufacturing areas and that effective and comprehensive Quality strategies and controls exist for applicable processes. Develop and manage the company's Quality Management System
- Understand and apply Quality tools, including DFMEA, PFMEA, IQ, OQ, PQ, GR&R/measurement system analysis, control plans, process verification/validation plans, validation protocol development, Cpk, Cp, SPC, operator work instructions, DOE, process data analysis and DMAIC.
- Provide guidance to project teams, suppliers and other disciplines to ensure compliance with company policies and procedures as well as medical device regulations. This will include providing formal QMS training on the QMS subjects of Design Control, Risk Management, Design Change Control, Validation and Quality Engineering.
- Author and approve engineering change controls as required.
- Lead the development of Quality Systems (focus on Quality Engineering, Validation, Risk Management and Design Control) compliant policies, procedures for US QSR and ISO 13485 and other applicable regulatory requirements.
- Coach, mentor, and develop your direct reports for a strong succession path
- Develop and implement the document control, equipment calibration and training systems
- Ensure tests and procedures properly performed and evaluated
- Lead quality system development and implementation throughout product life cycle
- Work with external consultants regarding the development and implementation of the company's quality system
- Conduct internal audits and external vendor audits
- Responsible individual for third party audits/inspections
- Implement supplier controls for the approved vendor list
- Participate in the development of protocols/reports in support of test method validations, design and process verifications and validations, biocompatibility, sterilization, shelf life, packaging, and risk management
- Lead and/or assist in thorough investigation and root cause analysis of Quality issues and effective corrective and/or preventative actions to ensure compliance with established Quality objectives and regulations.
- Lead compliance related activities, interface, and audits with regulatory agencies and notified bodies
- Provide oversight for internal and external metrology, incoming inspection, acceptance controls, disposition of non-conforming materials, and measurement system evaluations
- Schedule and lead management reviews
- Create and implement quality plans as needed
- Manage Investigations (including complaints), NCMR, and CAPA

- Interact with staff from various departments or contract manufacturers to implement quality procedures, validation points and quality metrics
- Serve as the primary manufacturing / quality contact for customer and third party audits.
- Assume as management representative

Skills/Job Requirements

Education:	Bachelor's degree or higher in engineering, science, technical or related field
Experience:	Experience in an FDA and ISO regulated environment
	About 10 years of related engineering experience, with 5+ years in the medical device industry
Knowledge/Skills:	Product development
	Design Controls
	Design Review
	Planning
	Risk Management
	Design verification and validation
	Test Method development and validation
	Statistics (not limited to DOE, ANOVA, Confidence and Tolerance Limits, SPC)
	Audit
	CQE