POTRERO MEDICAL

Position Title: Sr. Regulatory Affairs Specialist
Reports to: Director, Clinical and Regulatory Affairs
Department: Clinical and Regulatory Affairs

Please email 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. The department of Clinical and Regulatory Affairs is responsible for clinical/regulatory support for our current commercial device, expansion of this product into new markets and future products under development.

Job Description

Potrero Medical is looking for an experienced Regulatory Affairs Specialist to support all aspects of regulatory affairs within the company. In this role, he/she will provide tactical support by ensuring regulatory compliance for the current commercial product and strategic support for future products and markets. As the only full-time RA employee, he/she will take on a lead regulatory role at the company, have autonomous ownership over projects, and collaboratively work with the Director CA/RA with minimal supervision over day-to-day tasks. He/she should expect to go beyond the typical regulatory affairs responsibilities and enjoy cross-functional projects/roles.

General Roles and Responsibilities

- Provide regulatory support for current products e.g., review engineering changes, labeling, promotional material, and provide regulatory impact assessment (memo-to-file or submissions) as pertains to US and international regulatory requirements.
- Responsible for ongoing activities related to compliance with US and Global Regulatory directives and regulations including regulatory compliance for device feedback on commercial and clinical products (SAE/AE assessment, MDRs, vigilance)
- Manage submission activities for a variety of device regulatory approvals including
    - CE mark (creation and/or maintenance of product technical files including Clinical Evaluation Reports (CERs))
    - US submissions (Traditional and abbreviated 510ks, special 510ks, Pre-sub requests, IDE's, post-approval reports, annual reports, export certificates, and establishment registrations and device listings)
- Maintain regulatory files/database and chronologies in good order. Maintain system for tracking changes in documents submitted to agencies or partners
- With Dir. CA/RA, develop domestic and international regulatory strategy for new products
- Manage interaction with regulatory agencies on regulatory and technical matters, at all stages of product development, and review process to ensure submission approval
- Acquire and maintain current knowledge of regulatory requirements and scientific/technical standards applicable to Potrero products and markets
- Guide joint project teams through "regulatory landscape" by communicating submission requirements to the team and educate on new regulatory requirements through in-house seminars and updates to SOPs

Skills/Job Requirements

- Life Sciences/Health/Engineering Master's degree and 3+ years' experience preferred, or bachelors, RAPS certification and 7+ years' experience
- Experienced in medical device industry trends and practices
- Knowledgeable in all regulatory requirements pertaining to medical devices (e.g. ISO 14971, ISO 13485, 90/385/EEC, 93/42/EEC, ISO 14155, ISO 62366, IEC 60601-1, 21 FDA 21 CFR Chapter I, Subchapter H)
- Excellent written and verbal communication skills
- Comfortable with a fast-paced start-up environment with changing priorities
- Computer literate – Use of word processing and spreadsheets