POTRERO MEDICAL

Position Title: Sr. Clinical Research Associate (Sr. CRA)
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 Clinical and Regulatory Affairs department 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 Sr. Clinical Research Associate (Sr. CRA) to support all aspects of a clinical study operations. In this role, he/she would need to have extensive tactical experience with setting up clinical studies for a post-market device and interface very closely with engineering and marketing teams. As part of a small clinical team, he/she will have autonomous ownership over projects, and collaboratively work with the Director CA/RA with minimal supervision over day-to-day tasks. As is typical for a medical devices start-up he/she should expect to go beyond the typical CRA responsibilities, and enjoy cross-functional projects/roles.

General Roles and Responsibilities

- Ownership over the entire clinical study process from:
  - Study concept/protocol development in collaboration with Director CA/RA, and PIs, KOLs
  - Preparation of all study materials for IRB submissions (ICFs, CRFs, recruitment materials, IFUs)
  - Performing all study site maintenance activities including site qualification, site initiation, site training, monitoring, AE reporting, study progress reports, study close out
- Interface/collaborate with Marketing/Engineering to
  - Gather post market data for clinical evidence to support claims for market adoption of the current product
  - Work with the engineering team on the development/execution of clinical trials to support next gen devices
  - Provide customer feedback to engineering/marketing to iterate on technical implementation and development
- Negotiate site contracts (including budgets), and project manage internal/external resources to help with study
- Setup and management of data collection process including EDC set-up, data review and data clean-up
- Assess patient recruitment and retention including strategies to increase enrollment
- Serve as project/device expert to study site and internal team regarding the study device and clinical trial conduct
- Manage and maintain device inventory on site
- Ensure that study site / internal team conduct study in compliance with ICH/GCP principles, SOPs
- Perform source document verification and case report form review
- Perform adverse event and serious adverse event reporting and follow-up
- Assist with clinical literature searches, drafting clinical scientific justifications/memos and clinical data analysis

Skills/Job Requirements

- Clinical, Engineering, or life science Degree
- Master's degree and 3+ years' clinical trial experience preferred, or bachelors and 7-10+ years' clinical trial experience
- Extensive knowledge of GCP-ICH requirements for device research and development
- Preferred clinical experience in critical care/urology products
- 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
- Ability to travel up to 30%