Medibio Manager of Clinical Affairs

Medibio LTD is seeking a Manager of Clinical Operations at our Peninsula headquarters. The company is integrating biometrics and artificial intelligence to better diagnose and manage a variety of mental health conditions. Join a mission-driven, high-performing team to pioneer this important new frontier. As the Manger of Clinical Operations, you'll help build the clinical program from the ground up and will provide the operational leadership to drive the successful completion of the company's clinical studies.

The ideal candidate will be experienced in medical devices, expert in Good Clinical Practice, and flexible & inventive, in order to navigate the fluid environment of early clinical development, then grow the company capabilities for later-stage studies.

Here's a snapshot of the duties:

Primary Responsibilities

- Establish and champion the company policies and processes to ensure conformance with Good Clinical Practice
- Develop operational plans for studies ranging in stage from pilot to pivotal to post-approval
- Operationalize investigator selection and site management for multi-site studies
- Screen, select, contract with, and manage contract research organizations
- Lead clinical study data management activities
- Set and achieve clinical study quality targets, performance metrics, budgets and timelines
- Meet milestones for clinical study deliverables, including site initiations, completion of enrollment, database lock, and clinical study reports
- Support reporting requirements to IRBs, ECs, and regulators
- Support submissions to US and OUS regulatory entities
- Manage and develop junior clinical operations colleagues
- Travel: estimated 20%; international travel likely

Background & Experience

- 3+ years as a Manager of Clinical Operations for pilot & pivotal studies for medical device development (preferred) or Phase 2-3 pharmaceutical development
- RN, PhD, or MD preferred
- Experience directing or managing both early- and late-phase, multi-center studies
- Familiar with drafting and implementing clinical SOPs and best practices
- Facile with web-based Clinical Trial Database tools
- Experience coordinating cross-functional teams consisting of internal and external stakeholders
- Comfortable with vertical and horizontal 360° communication
- Oriented to detail, able to multi-task

- Competent in the use of budgeting, project management, Google Doc, and Microsoft Office applications
- Excellent verbal and written communication skills