

## **Program Manager (job level can be Director or Manager depending on experience)**

### **Job Summary:**

We're looking for a talented Program Manager who has the experience, dedication, and leadership skills necessary to help organize the design and production of our innovative neuromodulation system. We're a small, nimble, focused company with a team of highly dedicated professionals who are focused on creating a meaningful solution for patients with Acute Decompensated Heart Failure (ADHF).

### **Job Responsibilities and Duties:**

- Create and maintain the product development schedule. Continually identify critical path and use that information to identify areas of focus for the organization. Project schedule includes design, manufacturing, verification, and validation of the Pivotal system (including the Cardionomic catheter, an external stimulator, a software interface, implant accessories, and the manufacture or purchase of all components).
- Lead and organize discussions with external developer/manufacturer partners. Determine and communicate prototype and production needs (quantity and timing) to these partners. Monitor partner performance and help identify areas of focus if performance is deviating from plan.
- Complete quality system deliverables per company design control process
- Effectively serve as a member of the product development team by collaborating on all aspects of product development including Concept, Design, Verification/Validation, Clinical, Marketing, Quality, and Regulatory

### **Qualifications and Skills:**

- Required:
  - BS or MS in Engineering with 10+ years of experience working under FDA design control processes. Experience with regulated quality systems. Various engineering backgrounds are acceptable (Electrical, Mechanical, Software, Biomedical, Design Assurance)
  - Experience in managing the development of electrical catheter devices and/or chronic implantable devices and external controllers, covering all phases of development
  - Demonstrated experience creating and maintaining product development schedules with a focus on critical path identification
  - Demonstrated experience working with external developers and manufacturers. Ability to collaboratively resolve key issues with these partners.
  - Demonstrated experience producing design control deliverables such as Product Development Plans. Experience organizing, hosting and documenting development Phase and Design Reviews.
  - Ability to consume large amounts of information and determine the key areas of risk across the development and manufacturing effort. Ability to focus the organization on minimizing and mitigating these risks.
  - Excellent organizational skills
  - Excellent communication skills
  - Proficiency with project schedule software
  - Ability to work independently as needed
  - Capability to work in a fast paced, small company atmosphere. Ability to identify and evaluate inside and outside resources to accomplish tasks.

- Ability to fit well with Cardionomic's core values: Commitment to Quality, Collaboration, Candor, Competence, Closure
- Preferred
  - Experience blending quality system processes and deliverables between internal and external development and manufacturing organizations
  - Experience and comfort with pre-clinical and clinical activities, including procedure observation and concept evaluation
  - Ability to travel periodically to external developer and manufacturing partners as business needs dictate
  - Knowledge of basic cardiac functions