Principal or Senior Systems Engineer

Job Summary:
We're looking for a talented Systems Engineer who has the experience, dedication, and technical leadership skills necessary to help define, create, and implement the architecture of our innovative 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:
Own requirements definition, creation, and maintenance, from Stakeholder Needs to System and Subsystem Requirements and associated procedures and processes. Own tracing requirements to verification activities and risk mitigations. Own and oversee the Issue Tracking system and associated procedures and processes. Collaborate on complex problem-solving activities, periodically helping to implement solutions to complex problems. Participate in verification and validation planning and execution. Effectively serve as a member of the product development team by collaborating on all aspects of product development including Concept, Design, Verification/Validation, Clinical, Regulatory, and Commercial release.

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, Biomedical, Design Assurance) as long as candidate meets other qualifications.
    - Electrical and Systems Engineering experience in development of acute use electrical catheter devices and/or chronic implantable devices, covering all phases of development
    - Demonstrated experience owning requirements activities covering Stakeholder to System and Subsystem requirements involving complex electro-mechanical systems, including hardware and software elements
    - Demonstrated ability to lead discussions that resolve open questions, ambiguities, or disagreements regarding requirements. Ability and background to turn abstract requirements into implementable designs.
    - Experience writing requirements such that they are verifiable
    - Experience tracing requirements to applicable external standards and through verification activities
    - Experience performing verification and validation activities, including test method development
    - Experience owning and implementing requirements management software
    - Experience with Hazard Analysis and other risk management techniques
    - Experience implementing and overseeing an Issue Tracking system. Experience capturing issues and observations, putting them into an Issue Tracking system, hosting meetings to discuss/disposition issues, and leading discussions that culminate in closure of issues.
    - Strong organizational and communication skills
    - Ability to work independently as needed

    - Exercises substantial independent technical judgement in assigned tasks, work methods and goal interpretation
    - Capable of working in a fast paced, small company atmosphere. Able to identify and evaluate inside and outside resources to accomplish tasks.
- Preferred
    - Knowledge of heart failure, cardiac anatomy and physiology
    - Demonstrated ability to work effectively with physicians, clinical consultants and scientific advisors.
    - Experience working with contract engineering development organizations and blending quality system processes and deliverables between organizations
    - Experience and comfort with pre-clinical and clinical activities, including procedure observation and concept evaluation
    - Able to travel periodically, including some international travel. Required travel time will vary with project phase (less in development phases, more in clinical phase).
    - Experience with electronic device usability evaluations