**JOB POSTING**

**Software Engineering Lead - Medical Device R&D
LOCATION: Bedford, MA**

**OVERVIEW**

Vivonics, Inc. is seeking an experienced hands-on group leader, project manager and senior contributor to lead medical device development projects.

The Software Engineering Lead will be responsible for leading select government-funded R&D projects in novel medical device development, and providing functional leadership to electrical and biomedical engineers supporting these projects as well as those led by other project managers.

The ideal candidate will have broad and innovative skills that will allow them to work in a team environment to find solutions to challenging problems. They will work with senior scientists and engineers who provide subject matter expertise to translate high level concepts into solutions to realize novel device concepts.

**DUTIES AND RESPONSIBILITIES**

* Create and manage project schedules and plans, ensure that the tasks, milestones, and deliverables are accomplished on time and within budget.
* Use strong analytical skills to understand customer requirements, foresee technical challenges and lead the definition of design solutions to meet customer needs, manufacturability, cost, quality, reliability, regulatory requirements, effectiveness and safety.
* Work within a team of engineers and test personnel to produce high quality deliverables during the design, implementation, integration, test and support phases of product development.
* Responsible for the design, documentation, code construction, testing and maintenance of software applications for medical devices.
* Utilize the software configuration management system to correctly control and maintain software files.
* Produce and implement test plans to verify product functionality against requirements.
* Diagnose, debug and resolve defects; coordinate reviews.
* Prepare technical reports.
* Produce detailed design artifacts from technical requirements.
* Establish formal software testing including; unit and module test, subsystem test, and integration test to ensure correct software operation and quality.
* Communicate with sponsors, potential customers and Vivonics management.
* Produce design documentation in compliance with the Vivonics Quality System, regulatory requirements, and industry standards.
* Work with principal investigators and other project managers to plan technical approaches to projects.
* Work with multidisciplinary teams to deliver device solutions and products ready for pre-clinical or clinical trials.
* Manage internal and external resources to meet the design, build, test and manufacturing criteria.
* Participate in meetings and presentations with team members and sponsors and communicate ideas and engineering concepts to all disciplines.
* Support Business Development by contributing to project proposals and project planning.

**BASIC QUALIFICATIONS**

* **Experience in medical device product development under 21 CFR 820, ISO 13485,** IEC 62304, IEC 60601, and ISO 14971.
* BS in Computer Science, Electrical Engineering, Biomedical Engineering, or related field. MS or PhD is preferred.
* Minimum of 10 years of work experience is required.
* Strong software programming skills in C and/or C++.
* Solid foundations in data structures, algorithms and computer architecture.
* Hands-on experience on Embedded Systems.
* Experience programming for DSP architectures.
* Ability to contribute to multiple simultaneous projects with disparate requirements.
* **Strong project management, planning/organizational skills.**
* **Must be able to work in a team environment and learn new skills quickly.**
* The ability and enthusiasm to mentor less experienced staff.
* Excellent written and verbal communication skills.
* Ability to review the work of others.

**ADDITIONAL SKILLS AND REQUIREMENTS**

* **A successful track record in obtaining and managing government grants and contracts a plus.**
* Knowledge of Matlab or Labview for processing test results and test and measurement automation.
* Knowledge of requirements management.
* Experience with various integrated development environments.
* Working understanding of the application of risk management to medical devices.