**JOB POSTING**

**Mechanical 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 Mechanical Engineering Lead will be responsible for leading select government-funded R&D projects in novel medical device development, and providing functional leadership to mechanical 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 him/her 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.
* Generate concepts and system layouts in CAD
* Lead the detailed design of components, assemblies, and drawings.
* Prepare technical reports.
* 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 ISO 13485 and 21 CFR 820, FDA QSR.**
* BS in Mechanical Engineering, Biomedical Engineering, or related field. MS or PhD is preferred.
* Minimum of 10 years of work experience is required.
* Strong engineering design and development capabilities.
* 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.**
* CAD skills; Expertise with SolidWorks.
* 3D modeling.
* Knowledgeable in human factors and usability engineering.
* Working knowledge of Design for Manufacturing and Assembly.
* Working understanding of the application of risk management to medical devices.
* Quantitative mechanical analyses, including tolerance and stress analyses.
* Breadboard / Benchtop prototype development and integration.