The Senior Engineering Manager (SEM) will manage all activities within the engineering departments, including design, development, production and testing. This will require a strong technical leadership to develop, maintain, and improve our processes under design control. The EM will thereby lead and mentor the engineering teams, while overseeing robust project management processes to meet delivery timelines and budget specifications. The SEM will report to the upper management and work with all departments to discuss and lay out project specifications.

For the location in Cerritos (CA), BiVACOR is looking for motivated team members, who are keen to contribute to this active and dynamic project. This role requires creativity and flexibility to find the best strategy in a multidisciplinary environment. Strong leadership, organizational, time/project management, technical skills and experience in the field of medical devices are essential.

RESPONSIBILITIES

- Direct, review, and approve product design and changes under design control (FDA 21 CFR 820.30).
- Develop and implement policies, standards and procedures for the engineering and technical work performed in the company.
- Plan, implement, and direct corporate engineering, material control, and document control activities.
- Make detailed plans to accomplish goals with resources available.
- Confront and solve performance or operational issues to improve development efficiency.
- Perform administrative functions such as reviewing and writing reports, approving expenditures, enforcing rules, and making decisions about the purchase of materials or services.
- Plan and direct the installation, testing, operation, and maintenance of equipment.
- Recruit employees; train and mentor; assign and evaluate their work; and oversee the development and maintenance of staff competence.
- Check technical accuracy of work.

REQUIREMENTS

- Requires a bachelor's degree of engineering (or higher)
- 5+ years recent experience as an engineering manager
- Understanding of design requirements, verification, and validation for medical devices.
- Working knowledge of quality systems, risk management tools and applicable standards, such as 21 CFR Part 820 and ISOs 9001, 14708, 17025, 14971, 13485 is preferred.
- Excellent verbal and written communication skills with a demonstrated ability to communicate professionally in a global environment
- Must have critical thinking and problem-solving skills and be able to travel

Submit resume and cover letter to admin@bivacor.com