PROCESS ENGINEER (PE)

The Process Engineer (PE) will focus on product design and engineering of the BiVACOR TAH. Responsibilities will be to develop and optimize continuous production and manufacturing processes to achieve quality, and cost goals of the organization. The PE will manage daily Process Engineering activities by identifying process bottlenecks and devising solutions. You will recommend changes or upgrades to equipment, working methods, and other aspects of the process to improve efficiency and utilization of resources. The PE will work with internal engineering staff to create and maintain manufacturing schedules and manage suppliers.

For the location in Cerritos (CA), BiVACOR is looking for motivated and flexible team members, who are keen to contribute to this active and dynamic project. Strong organizational, time management, and technical skills paired with analytical and problem-solving thinking in a deadline driven environment is needed. This role requires the ability to work with minimal supervision and offers the opportunity for further career development. As a young company eager to advance, its products from laboratory to clinic, BiVACOR is committed to establishing processes that are supportive of ongoing R&D activities.

RESPONSIBILITIES

- Develop new manufacturing processes, procedures, inspection methods, and production layout for assemblies for the BiVACOR through frequent interaction with R&D, Quality Engineering, and Operations using project management, and design for manufacturability.
  - Assure processes comply with industry safety regulations.
  - Develop all manufacturing process documentation necessary to fulfill regulatory and Quality System requirements of both BiVACOR and external suppliers
- Perform equipment and process characterizations and qualifications (IQ/OQ/PQ).
- Manage required builds for new product development in a pilot or production setting, including training of operators, coordination with production planning, preparing manufacturing procedures and work orders, ordering materials, installing fixtures and equipment, supervising builds, and troubleshooting assembly issues.
- Follow FDA Medical Device Directives and other applicable standards
- Anticipating and mitigating risks throughout Project plans and management; proactively communicating issues to clients and internal teams.
- Create, edit, and maintain documentation related to design controls and quality system guidelines.
  - Assist in the development of design input specifications and study designs.
  - Write and review Standard Operating Procedures (SOPs) and Work Instructions (WIs).
- Some supervisory responsibility for junior engineers and technician staff.
- Lead pFMEA efforts to evaluate manufacturing process
- Interact with external suppliers
  - Participate in supplier visits.
  - Manage external suppliers as they conduct assembly work
  - Define, develop and implement processes and technical solutions to support current product designs, optimize manufacturing/reliability, and improve quality.

REQUIREMENTS

- Bachelor’s degree or higher in mechanical engineering with knowledge in process design.
- 3+ years of solid work experience in medical device development.
- Experience with electrical/mechanical systems for medical devices in a regulated environment.
- Understanding of design controls, including design (customer and product) requirements, performance specifications, and verification and validation testing.
- Project management experience.
- Familiarity with quality standards for medical devices

Submit resume and cover letter to admin@bivacor.com

BiVACOR, Inc.  www.bivacor.com  Cerritos, CA, USA