VALIDATION ENGINEER

The Validation Engineer (VE) will support the organization with all process validation related to the development and manufacturing of Class III Active Medical Devices (AIMD).

The VE will manage daily verification and validation plans for Medical Device Design functions (software, electrical and mechanical). The VE will actively perform and oversee testing activities by developing and performing verification & validation and will also complete inspection and assembly activities. The VE will work with internal engineering staff from mechanical, software and electrical engineering backgrounds to support development activities. The Validation Engineer will act as a liaison between the company and external vendors/suppliers to ensure manufacturing and testing activities are sufficiently undertaken to support product development and transfer to production.

For the location in Cerritos (CA), BiVACOR is seeking 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 an 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 career advancement.

As a young company eager to advance its products from laboratory to clinic, BiVACOR is committed to establishing validation and test practices that are supportive of ongoing R&D activities.

RESPONSIBILITIES

- Develop and execute verification and validation protocols based on system requirements and approved procedures and standards (ISO, IEC and FDA).
  - Supervise and perform inspection, assembly and V&V testing.
  - Design and build test fixtures, including support test fixture maintenance and calibration.

- Create, analyze, and summarize documentation related to verification and validation protocol results for FDA approvals and quality system guidelines.
  - Assist in the development of design input specifications and test designs.
  - Participate in Design Reviews and provide verification support to development teams (e.g. Code Reviews, Software Module and System testing, test automation, testing procedures)
  - Write and review Standard Operating Procedures (SOPs) and Work Instructions (WIs).

- With the internal and external QA personnel;
  - Assist in the documentation suitable for regulatory submissions,
  - Assist in conducting risk management activities and updating FTA, design and process FMEA.

- Interact with external suppliers/vendors.
  - Execute quality agreements and quality control plans in collaboration with suppliers.
  - Perform supplier audits and participate in supplier visits.
  - 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 Engineering (Software, Electrical or Mechanical), plus at least 2 years work experience in Class III medical device process development.

- AIMD design or validation experience highly desirable.

- Experience in Medical Device Industry and knowledge of engineering design, test and safety standards (IEC 60601-1, FDA, ISO)

- Understanding of design controls, including design (customer and product) requirements, performance specifications, and verification and validation testing.

- Strong technical writing ability for design verification/validation and reports.

- Previous experience in a Design Assurance role with experience through all phases (from product conception through commercialization) desirable.

Submit resume and cover letter to admin@bivacor.com