

## **ELECTRICAL ENGINEER (EE)**

The Electrical Engineer (EE) is responsible for leading a project in the electrical design and development and for providing support to the team during design, development, and software validation. Duties and responsibilities include, but are not limited to:

- Schematic design, PCB layout, FPGA utilization, part selection and ordering, create bill of materials for PCB Assemblies, reviewing of drawings, power distribution design, cable assembly design, hardware testing and software validation.
- Assist in new product development projects and cost-reduction design activities
- Collaborate (with mechanical and software team members) project development from electronic perspective.
- Establish and implement validation requirements for products, test methods and manufacturing processes
- Write assembly procedures and test procedures and records.
- Write process validation protocols and reports for new and improved manufacturing processes
- Write software validation protocols and reports for new and revised software applications.
- Work directly with customers, marketing, sub-contracted manufacturers, vendors and other engineering disciplines in the development and application of products and systems

This position will work closely with Quality Assurance including internal/external quality issue resolution, supplier quality issues, customer complaints, to drive process improvements. Duties and responsibilities include, but are not limited to:

- Create and maintain FDA compliant Design History Files (DHF)
- Provide root cause analysis support and drive the implementation of corrective action for process-related issues
- Execute process improvements as they relate to quality system compliance with FDA 510(K), QSR and ISO 13485
- Participate in complaint investigations, and failure analysis of products
- Provide support for continuous improvement of the quality management system.
- Create inspection processes for each individual item within the design assignment

## ***JOB REQUIREMENTS***

- Minimum of a Bachelor of Science in electrical engineering
- 5-10 years of experience with schematic design and PCB layout using Altium Designer or OrCAD
- Preferred familiarity with the medical device electrical safety & EMC requirements (IEC60601-1), regulatory (FDA & MDD) and Quality (QSR & ISO 13485) issues or similarly regulated industry
- Experience working within a company's Quality System is preferred
- Experience with, design specifications & requirements and verification & validation
- Experience with electro-optical and mechanical medical devices is preferred.
- Previously demonstrated project management skills
- Ability to work effectively in a team environment and build strong working relationships
- Ability to effectively problem-solve through critical thinking and root-cause analysis with minimal direction and make decisions with confidence
- Excellent organizational skills and attention to detail
- Strong communication skills, both oral and written
- Ability to prioritize, multi-task and adapt to change
- High degree of initiative and self-motivation with a strong sense of accountability
- This position requires 15% travel