Job Description – Test Fixture Engineer I, II, III

Reports To – Sr. Engineer, Manager of Engineering, Director of Engineering, Vice President of Engineering, or Chief Technology Officer

Job Responsibilities

Complies with Quality System requirements by engaging in appropriate levels GMP/ISO test methodologies, adheres to Quality System Design Control procedures, and applies proper documentation skills.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential job task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Is responsible for the design of test fixtures, considering factors like reliability, throughput, test coverage, product tolerances, test parameters, and ease of use.
- Creates and maintains design documentation for test fixtures which include design requirements, assembly drawings, and bill of materials.
- Creates and maintains supporting documentation for test fixtures including assembly instructions, operation procedures, calibration procedures, installation and operation test protocols (IOQs), and test reports.
- Oversees the manufacturing of test fixtures, including working with vendors and technicians to ensure accurate construction and documentation.
- Helps in the calibration and maintenance of test fixtures to ensure on-going accuracy and reliability.
- Analyzes test results, identify potential issues, and provide feedback to design teams for product improvement.
- Diagnoses and resolve issues with test fixtures during operation.
- Performs risk management activities per company SOPs.
- Actively participates in design reviews of his/her own designs and others' designs.
- Works as part of a project team or on an individual basis to refine existing specifications, develops process improvements, validation testing and makes yield enhancements and cost reductions.
- Performs systems engineering and component engineering activities.
- Ensures documentation is in accordance with Quality System requirements.
- Assists designing, writing, and performing test protocols, and produces test reports.
- Leads or trains Assemblers and Technicians.

Projects and Other Duties:

- Perform other duties as assigned

Position Qualifications

- Demonstrates proficiency in either Mechanical or Electrical engineering according to the engineering position level.
- Ability to adapt and learn quickly leveraging knowledge towards the contribution of projects.
- Ability to use Microsoft Office tools for documentation, analyzing data, presenting data or ideas, etc.
- Ability to use Microsoft Excel and other data analysis tools to manipulate and analyze data sets.
- Ability and experience in using the following test equipment: DVM, oscilloscopes, signal generators, hand tools, such as soldering irons, hand crimpers, screwdrivers, wrenches, and pliers.
- Ability and patience to analyze, debug and troubleshoot electronic circuitry is preferred.
- Competence in data processing or programming skills using Excel VBA, MATLAB, Python, or other similar languages is preferred.
- Competence in the use of CAD software such as Auto cad, SolidWorks, ProE is preferred.
- Competence in the use of Electronics CAD software for schematic capture and PCB layout is preferred.
- Professional, clear verbal and written communications skills required.
- Ability to work independently or in a team setting as required.

Minimum Education:

- BS in Engineering or scientific discipline or equivalent experience.

Minimum Experience:

- 0-5 years' experience in Engineering based on the engineering position level.
- Experience in designing, maintaining, and qualifying test fixtures for medical devices is preferred.
- Experience in or familiarity with manufacturing processes for medical devices is preferred.
- Engineering with Class II or III medical devices is preferred, though equivalent experience in other regulated environments is acceptable.
- Experience working under regulated quality systems such as cGMP's, ISO, and the MDR, commensurate with the engineering level.