



Job Description – Operations Engineer

Reports To – Director of Operations

Job Responsibilities

This position is responsible for contributing to the design, development and manufacturability of specific product(s) in accordance with the company's Quality System and customer requirements. This position will ensure that assigned projects and/or product(s) are designed for technology transfer from R&D to manufacturing and facilitate improved manufacturability. This position complies with the Quality System by engaging in appropriate levels GMP/ISO test methodologies, adherence to Quality System Design Controls, 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.

- Refines existing specifications, develops process improvements, creates validation testing and makes product yield enhancements and cost reductions.
- Researches and recommends vendor and material choices for product. Prepares and delivers status reports.
- Develops and implements quality inspection procedures, including sampling plans, for production level components and finished goods.
- Reviews and approves assigned controlled documents (e.g. work instructions, quality specifications, engineering specifications, procedures and validations protocols). Ensures that product documentation is in accordance with Quality System requirements.
- Maintains compliance of quality related logs and records, including but not limited to, CAPA, NCR, ASL, CAL/PM, and Training.
- Establishes, implements, and maintains company Quality System in compliance with FDA, International Standards (ISO), and other regulatory agencies.
- Manages communication and acts as supporting liaison with regulatory agencies on compliance issues, including registration and licensing of facilities and regulatory agency audits and inspections.
- May work directly with the company/customer representative to determine needs in product repairs, complaints analysis and user interface. May provide assembler/operator training and contribute to the development of support materials as required.
- Researches, designs, and develops new processes and current product enhancements in accordance with Quality System requirements.
- Provides input regarding appropriate statistical methods, test methodologies, test facilities, and equipment.

Projects and Other Duties:

- Perform other duties as assigned.

Position Qualifications

- Skilled in the use of CAD software such as Auto cad, SolidWorks, and/or Pro E.
- Knowledge of and exposure to product testing and data collection
- Familiar with Design Control procedures and requirements.
- Knowledge of and exposure to product testing and data collection.
- Ability and willingness to travel
- Ability to detail project plans effectively

Minimum Education:

- Bachelor's degree in a relevant engineering discipline such as Biomedical Engineering, or equivalent experience.

Minimum Experience:

- 3 years in medical device design or similar products, Class II or III devices preferred.
- Experience working under regulated quality systems such as cGMP's, ISO, and the MDD.

Work Environment & Physical Demands of the Job:

- The noise level in the work environment is usually quiet. While performing the duties of this job, the employee is regularly required to remain in a stationary position at least 50% of the time; operate computers and other office equipment; and communicate and exchange information. The employee is occasionally required to reach with hands and arms and to move within and between the buildings. A computer terminal is used to access, input, and retrieve data. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision.
- The job requires travel by air, train, and car travel, sometimes for long distances and extended periods of time.

Additional Important Information:

- Axonics may make reasonable accommodations to enable individuals with disabilities to perform the functions of this job, unless doing so would result in an undue hardship on Axonics.
- This job description is subject to change and management reserves the right to assign or remove duties and responsibilities of this job at any time.