

RxFunction Job Posting Quality Engineer

About RxFunction™

RxFunction is a privately-held start-up medical device company headquartered in Eden Prairie with a mission to design and bring to market medical technologies that restore balance, increase mobility, and enhance confidence.

RxFunction is the sole provider and manufacturer of Walkasins®, which is a prescribed wearable sensory prosthesis enabling patients with Sensory Peripheral Neuropathy to improve walking balance and subsequently decrease risk of falls. Peripheral neuropathy is a condition estimated to affect over 20 million Americans.

Position Summary

The Quality Engineer will be responsible for supporting the quality department in overall product quality and compliance initiatives. The Quality Engineer must work independently and be capable of leading quality improvement projects and performing product quality investigations.

Job Responsibilities

Responsibilities include, but are not limited to, the following:

- Analyzing complaint data and performing root-cause-investigations.
- Develop corrective action plans and implement corrective actions related to product quality.
- Develop test methods for product testing and investigations.
- Assist in maintaining the post-market quality management system, including complaint investigation management, entering information into the complaint database, and providing post-market data reports to appropriate management.
- Supports the site quality manager during quality system audits including FDA, Notified Bodies, or other regulatory bodies.
- Performs return goods analysis and prepares analysis reports.
- Supports medical device operations such as performing incoming quality control analyses and completing device history records.

Required Qualifications

- 1-2 years experience as a Quality Engineer in the medical device industry or equivalent.
- BA/BS degree in science or other technical field.
- Thorough understanding of medical device regulations, including FDA medical device regulations 21 CFR part 820 & ISO 13485.
- Strong leadership, communication, writing, and organizational skills.
- Excellent attention to detail.

Preferred Qualifications:

- Experience participating in internal and external audits (FDA, notified body, supplier audits)
- Experience in biomedical, mechanical, or electrical engineering.
- Experience in test method development and execution.

Physical Requirements:

The physical demands described within the Responsibilities section of this job description are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is regularly required to be independently mobile. The employee is also required to use a computer and communicate with peers and co-workers.