RxFunction

Balance. Mobility. Confidence.

RxFunction Job Posting: Director of QA / RA

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.

Our first product is Walkasins®, an innovative, non-invasive lower limb Sensory Neuroprosthesis for people with sensory peripheral neuropathy who have gait and balance impairments. Peripheral neuropathy is a condition estimated to affect over 20 million Americans. Walkasins is manufactured in Minnesota and will be sold mainly through healthcare systems to prescribing clinicians in neurology, physical medicine and rehab, and physical therapy; and referral clinicians in diabetes and oncology. RxFunction, Inc. has recently registered and listed Walkasins® with the FDA, but Walkasins is not yet available for sale.

The co-inventor and current CTO developed this technology at Boston University and founded the company in 2010, receiving $1.3 million in grant funding from the NIH to further develop and clinically evaluate the Walkasins technology. RxFunction has completed a successful $7.5 million Series A round of funding.

To join our innovative and fast-growing organization and become part of our dedicated team, please apply by emailing your resume and cover letter to **HR@rxfunction.com**.

Position Summary

As the Director of Quality Assurance and Regulatory Affairs, this position will be responsible for ensuring global leadership in RxFunction, influencing the creation of and meeting the global regulatory requirements for the company's emerging medical device initiatives. This position will interact with the FDA, Notified Bodies and other approval authorities as needed to develop the regulatory strategies for and manage all aspects of their execution for this novel therapy.

This position is responsible for ensuring the overall effectiveness of the quality system throughout the organization, including its ongoing compliance to regulatory requirements. It reports to the CEO and works with all critical functions of the organization.

Job Responsibilities

As the Management Representative, this position is responsible for and has authority that includes:

- Ensuring that processes needed for the quality management system are documented, implemented and maintained.
- Reporting to executive management on the performance and effectiveness of the quality management system and any need for improvement.
- Ensuring the promotion of awareness of the QMS and applicable regulatory requirements throughout the organization.

  Other responsibilities include:

- Perform or verify performance of direct reports on completion of QMS duties including but not limited to: specification and process development and implementation, material, part and device inspection and non-conforming materials handling in collaboration with operations, feedback / complaint handling in collaboration with customer service, and CAPAs in collaboration with all departments.

- Prepare and lead the QMS Management Review meetings which includes preparation and distribution of reports regarding the quality system, quantification the organization's performance relative to quality objectives and overall QMS effectiveness.
- Function as liaison with external parties on matters relating to the quality management system such as quality audits by outside parties.
- Oversee the documentation of activities to show evidence of compliance with requirements of applicable customers, registrars and regulatory agencies.
- Provide leadership, supervision, and development opportunities to direct reports.
- Oversee, plan and execute internal quality and supplier audits.
- Implement continuous improvement programs using problem analysis and resolution skills.
- Function as the organization's subject matter expert relative to applicable international standards and regulatory requirements.
- Plan, recommend and facilitate QMS-related training throughout the organization.
- Employ effective, respectful and persuasive spoken and written communication skills.
- Ensure compliance with work instructions and Quality Management System (QMS) procedures.
- Ensure effective staffing, wage, development and performance decisions.
- Maintain highest levels of ethics and confidentiality.
- Collaborate on the development of the global regulatory strategy for medical device products. Ensure the strategy's implementation.
- Partner with the R&D, Operations, Clinical Affairs and all departments in the development and implementation of company and supplier processes and strategies to meet customer requirements and regulatory requirements.
- Interact with the FDA and other approval authorities to facilitate global approval of an emerging technology. Manage all communications with all regulatory agencies; represent the company to agencies and trade associations.
- Hire and develop the Regulatory Affairs and Quality Assurance teams.
- Facilitate new product development through a committed partnership with development teams throughout all phases of the product development process with particular focus on customer requirements, risk management, verification and validation and using statistical techniques for sample plans.
- Effectively manage the Regulatory Affairs team to ensure on-time submissions, registrations, licenses and approvals that support the business.
- Prepare annual Quality and Regulatory department budget in coordination with Finance department.
- Other duties and responsibilities may change or be assigned at any time with or without notice.

Required Qualifications

- A Bachelor's degree in a related science or engineering discipline required.
- 10+ years' experience in Quality and/or Regulatory within the medical device industry, with 5+ years of supervisory experience, and commensurate experience in FDA-regulated medical device Design and Development, Quality Control, and Risk Management, Supplier Audits, CAPA and Complaint Handling.
- Extensive knowledge of global regulatory for medical devices.
- Proven track record of managing positive interactions with the FDA and other regulatory authorities, in addition to ensuring that standards of communication and correspondence with regulatory bodies are maintained and documented.
- Experience working effectively with teams within an organization.
- Knowledge and experience in the implementation of Continuous Process Improvement, Lean and Six Sigma.
- Thorough understanding of the latest versions of applicable medical device standards including ISO 13485, 14971 and FDA medical device regulations.
- Strong leadership, communication and organizational skills.
- Full understanding of manufacturing and operational systems.
- Ability to travel up to 20% with both car and plane.

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Preferred Qualifications:

- MBA or other relevant advanced degree.
- Regulatory Affairs Certification by RAPS.
- ASQ certification

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.