Interested Parties should contact:
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Position: **Director, Quality** **Location:** **MA**

Our client is a pioneering biotechnology company in the emerging field of regenerative medicine. Their goal is to regenerate and restore organ function of the esophagus, trachea or bronchus damaged by cancer, trauma, infection or congenital diseases.

The company's novel technology is engineered to stimulate the body's signaling pathways and natural healing process to regenerate and restore organ function. The technology is based on over 20 years of scientific progress in the fields of tissue engineering, cell biology and material science / combining the best attributes of a synthetic scaffold with tissue engineering and cell biology to create what may be a revolutionary method of addressing organ damage.

Job Summary

The primary responsibility of the Director of Quality Assurance (QA) is to establish, develop and manage the company's quality management system (QMS) in compliance with US regulations and standards for Combination Products (Medical Devices and Biologics/Cell Therapy). The Director of QA plans, executes activities related to all aspects of Quality Assurance that include but are not limited to Quality System and Product Quality Activities. Ideally - we are seeking an experienced QA professional with experience in both medical device and cell product (Combination Product) compliance.

Responsibilities

- Builds the Quality Department infrastructure to assure compliance to company, industry standards and the applicable regulatory requirements.
- Ensures the QMS is capable and effective at all levels; achieves and maintains compliance to US and international standards at our Holliston, MA facility.
- Interfaces with external personnel (vendors, partners and regulatory bodies) and internal personnel (management and staff) to drive Quality Assurance tasks and milestones.
- Responsible for audit planning (including Supplier audits), conduct, findings, responses, and corrective and preventative actions.
- Performs and directs quality system internal audit activities and drives improvements within the local quality system, as needed.
- Monitors the performance of quality systems and reports to management on a periodic basis.
- Designs and implements a phase-appropriate QMS for a combination product in an organization with both internal and outsourced manufacturing.
- Supports quality management sub-systems to achieve continual compliance and consistency in: management reviews, CAPA, design, design change, document control, process control, complaints, training, etc.
- Fosters an open environment to continually improve the Quality System.
- Responsible for oversight of Document Control and Employee Training programs.
- Influences effective compliance based decisions with cross functional communication and team building skills.
- Assimilates relevant technical, regulatory, and compliance information to formulate suitable strategies and tactics to satisfactorily resolve complex problems.

- Establishes Quality System goals and objectives and applicable Quality System metrics.
- Conducts periodic reviews of the state of effectiveness of the Quality System with Executive Management.
- Promotes awareness of regulatory compliance and customer requirements throughout the organization.
- Works closely with other departments to ensure Quality System and Product requirements compliance.
- Acts as the Quality Management Representative for the company.
- Responsible for recruiting, building, managing and leading a high performing, knowledgeable Quality Departmental staff.
- Lead cross-functional implementation of applicable standards and regulations.

Qualifications

Bachelor Degree required; ASQ or RAPS certification is a plus.
10+ years of quality experience in the medical device industry, Combination Product experience preferred.
Working knowledge of compliance best practices for cell-based products.
Understanding of compliance nuances related to Combination Products.
Strong knowledge of US Quality System requirements.
Strong Team-working and communication skills. A drive to get the job done.
Self-directed and able to apply problem solving methodologies.
Ability to achieve Company milestones.
Experience dealing directly with FDA and notified bodies and knowledge of appropriate FDA, ISO, and global regulations regarding quality systems is a plus.
Ability to effectively communicate with a broad spectrum of people having varying backgrounds, education, and experience.
Ability to act as a change agent and drive/influence change as well as effectively lead and motivate team members to achieve goals.
Demonstrated success in delivery of key milestones against tight timelines.
Aptitude to succeed in the culture of a fast-paced, publicly traded, start-up biotechnology company.