Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120

Position: Senior Quality Engineer 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

Develops, establishes and maintains Quality Engineering methodologies, systems and practices which meet the applicable regulatory requirements and procedures. Serves as a Quality representative to improve awareness of the regulatory and requirements to the different functional areas. Communicates quality initiatives in support of departmental, functional quality goals and priorities. Provides Quality Engineering support to the product development, manufacturing and Quality System team.

Responsibilities

- Provides leadership role on championing Quality and cross functional engineering initiatives.
- Provides QE project direction, coaching and mentoring to the R&D team.
- Provides guidance and support in generating product development documentation (dFMEA, pFMEA, product specifications, risk analysis, design verification protocols, reports, etc).
- Generates documentation as related to Design Controls (SOPs and product specific documents).
- Proactively investigates, identifies and implements best-in class QE practices.
- Identifies and implements effective process control systems to support the development, qualification, and manufacturing of products in compliance with cGMP requirements.
- Leads and mentors the product development and manufacturing teams through the Design Control requirements.
- Ensures that all Design Control requirements are met during the product development process.
- Assures the development and execution of systems which effectively identify and resolve quality issues.
- Assimilates relevant technical, regulatory, and compliance information to formulate suitable strategies and tactics to satisfactorily resolve complex problems.

Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120

Qualifications:

- Bachelor Degree required; ASQ or RAPS certification is a plus.
- 5-8+ years of quality experience in the medical device industry; combination product experience is a plus.
- Working knowledge of compliance best practices for medical device products.
- Understanding of compliance nuances related to Combination Products.
- Strong knowledge of US Quality System Regulatory requirements.
- Strong knowledge of Risk Analysis and related tools.
- 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.
- Strong written and verbal communication skills.
- Strong technical writing skills.

Additional Information

- The Sr. QE will report directly to the Director of Quality.
- Minimal travel may be required (10% or less).
- Must be able to work in a team environment and with minimal supervision.
- We offer an excellent salary and benefits package including medical, dental and vision coverage, as well as life insurance, disability, and 401K with company match.