tealbio

POSITION DESCRIPTION

Job Title: Quality and Regulatory Engineer
Reports to: Chief Technology Officer
Revised date: 8/20/2021

Teal Bio is an early-stage medical device company whose mission is to bring superior sustainable personal protective equipment to healthcare workers. Our first product, a reusable N95 respirator platform, will be available on the market soon. Creative and clever people committed to the company's mission are what power Teal Bio.

We are seeking a **full-time Quality and Regulatory Engineer** to drive the company's quality and regulatory activities. This position will be based in Somerville, MA. You will be the company's primary point person for all quality assurance and regulatory affairs activities.

The job:

- Maintain the Teal Bio quality management system
- Manage key quality metrics to track and improve compliance performance
- Effectively monitor key suppliers and contract manufacturers to meet QMS objectives
- Handle SOP documentation and record keeping
- Prepare regulatory submissions to NIOSH, the FDA, and other applicable regulatory bodies, in coordination with outside regulatory consultants
- Develop, monitor, improve, and maintain documentation to ensure compliance with ISO13485, 21 CFR Part 820, and NIOSH requirements
- Project manage all pre- and post- launch regulatory activities
- Manage supplier quality, including through audits and inspections
- Serve as the team expert on the contents and interpretation of various regulatory requirements to which Teal Bio is subject
- Represent the quality and regulatory affairs perspective in all phases of the product life cycle, including design, implementation, V/V, CAPAs, and nonconformances

You:

- Have quality and regulatory experience in the medical device industry
- Are familiar with GMP, FDA Inspections, FDA 21 CFR 820, and ISO 13485
- Are a regulatory/quality generalist willing to work on diverse projects
- Have a bachelor's degree or higher in engineering or a scientific field
- Demonstrate excellent project management skills

Relevant experience in the following areas is a plus:

- NIOSH regulations and applications
- Working with contract manufacturers
- eQMS software like Greenlight Guru