VITAL THERAPIES®
TARGETING LIVER DISEASE

Senior Manager, Quality Assurance

We are currently seeking a Senior Manager, QA to provide guidance for Biologics and Device Manufacturing, Supply Chain Quality, and Validation activities.

This person will be responsible for all quality activities to support the product life cycle, from development of new products from concept through commercialization. Ensures compliance with FDA and EU regulations, corporate directives, and related standards and Company strategies.

Essential Duties and Responsibilities include, but are not limited to:

- Manage Quality Events associated with VTL Biologic and Device manufacturing operations.
- Processes to include but not limited to manufacturing deviations, failure investigations, CAPAs, clinical incident reports, complaints and supplier audits.
- Perform validation assessments to support the VTL Change Control process
- Responsible for the QA review and approval of equipment, process and method validation reports
- Support vendor qualification process and quality systems.
- Control and direct RMAs investigation and closure in a timely manner.
- Create reports for Management Review and other trending charts to provide timely feedback to quality management, and manufacturing departments.
- Lead root cause investigations.
- Provide technical leadership and quality perspective on design assurance requirements and activities for project teams. Activities include but not limited to Verification and Validations, Planning, Risk Assessment/Analysis, Review of Test Protocols, and Technical Design Reviews.
- Generate and approve validation studies, capability studies, FMEA and Hazard analysis, and collaborate with engineering, manufacturing, and regulatory.
- Reviews all Device change orders to ensure compliance to Quality System, QSR and International requirements for New Product Development (NPD) and Sustaining activities.
- Provides mentorship to Quality Associates
- Provides coaching and guidance to R&D and Manufacturing personnel on Quality System Requirements.
- Ensure compliance to cGMP requirements.
- Ensure compliance with the quality system and all relevant internal procedures and policies.

Essential Duties and Responsibilities include, but are not limited to (Cont.):

- Ensure that all responsibilities within the scope of this job comply with the scope of company's Quality System.

Position Requirements:

Education and Experience:

- Bachelor's Degree in Science, Engineering or equivalent experience
- Minimum 8 years related experience and 1-3 years of experience in medical device, pharmaceutical or biotechnology industries
- Must be able to provide and implement solutions to quality problems
- Understand the impact of GMP's and regulatory requirements on company's new products.
- Strong working knowledge of Design Controls, manufacturing process controls
- Successfully worked with suppliers and/or subcontractors in implementing corrective actions and improving the quality of the delivered items and processes
- Strong computer skills required (Word, Power Point, Excel required)
- Strong analytical, communication and interaction skills
- Up to 10% Travel.

Physical Requirements:

Physical demands described here 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.

Regularly required to sit and talk and hear. Employee frequently is required to use hands to finger, handle, or feel. Employee is occasionally required to stand, walk, and reach with hands and arms.

Occasionally required to stoop, kneel, and lift up to 50 pounds. Frequently required to work on a computer up to 8 hours a day.

We offer a fast-paced work environment, competitive compensation, and a comprehensive benefits package.
Qualified candidates may submit **resumes** to careers@vitaltherapies.com

We are an Equal Opportunity Employer.