VITAL THERAPIES®
TARGETING LIVER DISEASE

## Manager, Quality Assurance

We are currently seeking a QA Manager who will be responsible for managing quality assurance, making continuous improvements, managing metrics and a diverse group of personnel. Drafts, reviews and approves SOPs, as necessary.

Supports internal and external audits/site inspections for GMP regulated activities. Works closely with company management team to ensure all aspects of the Quality Assurance process are completed within the accepted timeframe, maintain appropriate and secure files of laboratory documents and SOPs, assist with document control database updates, maintain manual documents for approval, promote active QA manual documents, and format QA manual documents per requirements, and assist with maintaining equipment and calibrations on a timely basis.

Provides Change Control guidance/oversight by working with Change Control authors and impacted sites. Provides input/assessments for implementation plan execution when necessary. Reviews and approves change controls related to PDMS manufacturing, laboratory and facility systems. Ensures effective and timely closure of Change Controls, and follows up to ensure effectiveness of the changes. In support of Maintenance program, consults on: work requests, work orders, calibration extensions and change requests, corrective and/or preventive maintenance.

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

- Maintaining and improving Vital Therapies quality system, assuring standards and activities are in line with our business philosophy.
- Develop and administer quality assurance procedures and activities to ensure VTL products are in compliance with quality standards.
- Assist in defining validation strategy and test methods to support equipment and product transfers.
- Identify required equipment and maintain equipment status in Product Verification test lab.
- Oversee CAPA, deviations, NCMR, and product complaint systems and ensure discrepancies are properly documented, investigated and completed in a timely manner.
- Generates and coordinates Quality Agreements and Supplier Agreements with suppliers.
- Interface with regulatory agencies during routine audits.
- Maintain and manage CAPA process.
- Oversee process line audits.
- Manage product verification and product release.

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

- Identify quality assurance resource requirements and manage deployment of resources to provide coverage for ongoing production activities.
- Implement an effective production line audit program.
- Develop system to collect, report, and identify actionable trends for critical product parameters.
- Integrate production operations results into management review activities.
- Manage personnel ensuring growth and professional development.
- Maintain approved suppliers list and critical supplier lists.
- Coordinate and perform and external supplier audits.
- Oversee release of incoming raw materials and final product release.

**Position Requirements:**

Education and Experience:

- Bachelor's degree in engineering preferred, master's degree a plus, or a minimum of 6 years' experience with in medical device and/or pharmaceutical manufacturing role
- Must have a background in manufacturing, operations or product development in a medical device and/or pharmaceutical manufacturing role
- ASQ Certified Quality Manager, Quality Engineer, Quality System Lead Auditor, or related quality/regulatory certifications a plus
- Knowledge of the FDA's Quality System Regulations; experience working within a Quality Management System
- Ability to prioritize, plan & evaluate deliverables to established strategic goals
- Strong management and leadership skills to ensure management, growth and development of personnel
- Previous supervisory experience preferred
- Excellent verbal and written communication and presentation skills with the ability to communicate business issues in English in an easy to understand manner
- Demonstrated experience prioritizing conflicting demands in an extremely fast paced environment
- Strong problem solving, influencing and negotiation skills, ability to work well as a leader, independently and in a team setting
- Strong working knowledge of Medical Device regulations, such as FDA 21 CFR 820, ISO 13485; MDD; CMDR; MDD 93/42/EEC and other applicable regulatory requirements.

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.

Position Requirements (Cont.):

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.

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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.