Vital Therapies is hiring! www.vitaltherapies.com

We are an exciting life science company located in the Carmel Mountain Ranch area of San Diego. Vital Therapies is a pioneer in the treatment of acute liver failure. We are currently seeking a **QA/Document Systems Management (Senior Specialist - Manager*)** to coordinate, implement and/or improve, and maintains the company's Document Control and Training System. Coordinates labeling activities through change management interfacing with suppliers to meet quality standards and timelines. Implement, configure and maintain electronic documentation management systems (currently Master Control). Provides guidance and coaching to users of the change order process.

Position Overview:

- Responsible for overall coordination of controlled documentation within the company.
- Performs the Document Control function within the validated Master Control system.
- Collaborates on, researches, analyzes, and verifies change orders submitted to Document Control.
- Ensures completeness and accuracy of information contained in all documents, document files, databases, and documentation systems.
- Review validation protocols, data and reports, as assigned.
- Coordinate assigned quality systems, such as GMP training program, deviations, CAPAs, or change controls.
- Implement improvements in quality systems and SOPs
- Review and update assigned documents, such as SOPs, , including line clearances, and shipment verification, equipment qualification and documentation control
- Coordinates and chairs Change Control Board meetings.
- Orders external standards and maintains tracking system.
- Assist in supporting audits, coordinating activities in backroom and ensuring timely response to documentation requests for auditors.
- Supports user requests for documentation and trains users in Master Control.
- Supports change management of labeling and ensures accurate completion of Labeling Verification form.
- Performs self-audits of satellite DMR locations and ensures that the current revision is available in a timely manner.
- Administers training system in Master Control, setting up users and exams as required.
- Maintains quality records per applicable SOPs.
- Investigates and responds to corrective actions related to Document Control, Training and External Standards.
- Responsible for coordinating document change orders (DCO), facilitates review, approval, and retention of Risk Management documents.
- Other duties may be assigned as deemed necessary.

Education, Training, Skills and Experience Requirements

- Bachelor's Degree in Science or related field **and** a minimum of 3 years' experience in the GMP / Manufacturing setting **or**

- Associates Degree in Science or related field **and** a minimum of 5 years' experience in the GMP / Manufacturing setting
- Documentation Management experience or Certificate in Configuration Management
- Previous experience in Document Control/Configuration Management is required (Master Control preferred)
- Knowledge and experience with CE marking, labeling standards and practices is desirable.
- Exercises judgment within broadly defined practices and policies in selecting methods, techniques and evaluation criteria for obtaining results
- Strong verbal, written, organizational, time management and interpersonal skills.
- Strong computer skills, including working knowledge of MS Office and e-mail.

We are an Equal Opportunity Employer. VTL offers a fast-paced work environment, competitive compensation salary and comprehensive benefits package