Vital Therapies is hiring! We are an exciting life science company located in the Carmel Mountain Ranch area of San Diego. Vital Therapies is a pioneer and recognized world leader in the treatment of acute liver failure. We are expanding our team and are currently hiring a **Project Manager** for our **Regulatory** team.

Position Summary

The Regulatory Affairs Project Manager will be responsible for the project management of regulatory submissions and operations activities as related to the company's new original market application(s) and all IND submissions to the U.S. and worldwide health agencies. This entails the coordination, prioritization and tracking of project submissions. This may include support for both products in early and late stage development and marketed products. The incumbent will apply advanced project management expertise and regulatory skills to guide cross-functional teams and demonstrates strategic thinking and creativity in support of clinical and CMC development programs.

Position Overview:

Develop and maintain detailed timelines for cross-functional regulatory submission activities and submissions, and assures planning and coordination of activities in a matrixed team environment.

Lead Regulatory Project Management roles and responsibilities to Clinical and CMC development teams:

- Provide global strategic input in terms of resource allocation across functional areas, submission operation, identification and mitigation of risks that have impact on deliverables and timings in accordance to departmental and corporate timelines.
- Foster effective and productive communications among various functional groups including CMC and Clinical Regulatory Leads, Labeling, Advertising and Promotion, Regulatory Operations, Medical Writing, Quality, Manufacturing, Medical Affairs, and representatives from other departments as appropriate.
- Assure that regulatory submissions are prepared in high quality manner according to defined Corporate or Regulatory timelines, and for working with Regulatory Leads (Clinical or CMC) to assure that submissions are prepared in line with ICH requirements, other local or regional regulatory requirements, as applicable, and company policies and procedures.
- Track timelines and deliverables for the original market application (BLA), regulatory commitments and timelines for maintenance activities such as IND Annual Report, DSUR, IND Amendments, Post-marketing Commitments and Follow-up Measures.
- Support all Company initiatives as identified by Management and in support of Current Good Manufacturing Practice (cGMP), Quality Management Systems (QMS), Environmental Management Systems (EMS), and other regulatory / compliance requirements.
- Comply with U.S. FDA and international regulations, other regulatory requirements, Company policies, operating procedures, processes, and task assignments.
- Maintain positive and cooperative communications and collaboration with all levels of personnel, customers, contractors, and vendors.
- Assists with project management for regulatory audits and inspections, if required.

<u>Education and Experience</u>

- Bachelor's degree in a relevant discipline
- 5-7 years of relevant experience are required; Strong Project Management skill sets with focus on biologics and combination products, being familiar with US device regulations required
- Prior BLA filing experience desired
- Must have working knowledge of regulatory requirements specific to US and EU, and preferably have a general awareness of requirements for other regions
- Excellent verbal, written, negotiation and interpersonal communications skills are required

- Excellent organizational skills and ability to work on a number of projects with tight timelines are required
- Incumbent must be proficient in the use of MS Suite, especially MS Project, XL Spreadsheet and PowerPoint

Physical Requirements**:**

The 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. The employee frequently is required to use hands to finger, handle, or feel. The 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, a competitive compensation, and benefits

Vital Therapies Inc. is an Equal Opportunity Employer

www.vitaltherapies.com