VITAL THERAPIES®
TARGETING LIVER DISEASE

# Job Description

**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 in the treatment of acute liver failure. We are expanding our team and are currently hiring a **Senior Director of Regulatory Affairs.**

**Position Overview:**

The Senior Director of Regulatory Affairs will identify, review and anticipate emerging regulatory issues and oversee global regulatory submissions in compliance with applicable regulations.

The Senior Director will develop and implement regulatory strategies for an investigational cellular therapy regulated as a biologic/medical device in accord with 1) FDA drug/biologic and medical device regulations and 2) European human medicines/Advanced Therapy Medicinal Product (ATMP) regulations and the European Medical Device Directives.

This role will also establish effective dialogue with U.S. and International regulatory authorities, direct the planning and preparation of regulatory submissions, including license applications, for the company's products and facilitate timely product registrations and regulatory approvals. The Senior Director will facilitate cross-functional communication regarding key regulatory filings and provide guidance to and develop regulatory staff.

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

- Executing global regulatory health authority strategy for new product development
- Executing global regulatory health authority strategy for combination drug/device product licensure
- Leading project teams for key regulatory filings to support new product development
- Educating cross-functional teams on purpose and scope of proposed or planned regulatory submissions to drive new product development
- Providing oversight in taking innovative ideas from proof of concept through regulatory strategy, including product development, manufacturing, filing and approval, and commercial operations
- Monitoring the US and international regulatory environments, and provide executive management with assessments of the impact of new and changing regulations
- Regulatory functions including planning and filing of documentation with domestic and international regulatory agencies
- Obtaining/generating information to be submitted to regulatory authorities and prepares required regulatory submissions
- Acting as liaison with appropriate local, national and international regulatory authorities
- Collaborating with the Quality organization in driving compliance activities related to FDA and ISO regulations, and quality system standards activities
- Leading relevant project planning and review meetings; conducts the final company document review and corrections
- Identifying and ensuring the establishment and monitoring schedules for submission documentation, review of documentation, protocols and reports received; prepares additional written materials needed
- Coordinating the preparation of 510(k) Premarket Notifications, IDEs, PMAs, CTAs, IMPDs, Design Dossiers, Technical Files and other International Registrations

- Preparing responses to FDA letters, supplements, and amendments; participates in FDA inspections and presentations as required
- Provide oversight and direction to regulatory consultants/vendors to ensure completion of deliverables and appropriate local VTL sponsorship, if applicable
- Writing department SOPs and implementing training programs for direct reports and other functional groups to assure awareness of all requirements and maintain compliance with all current regulation
- Participating in the preparation of the department's budget; ensures that the department operates within capital and expense budget guidelines
- Maintaining oversight of pharmacovigilance and product labeling activities
- Reviewing product complaints for reporting as required by relevant agencies
- Performing all other related duties as directed by management
- Developing guidance for internal staff

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**Position Requirements:**

Education and Experience:

- Ph.D. with 5-7 years related experience; Master's degree with 8 to 10 years related experience; Bachelor's degree with 10 to 12 years of related experience, and/or equivalent combination of education and experience, in preparing regulatory submissions for device AND drug or biologic products. Degree preferably in science or other technically related field or equivalent. Regulatory Affairs Certification (RAC) preferred.
- Proven ability to prepare and submit documents to global health authorities, including Biologics License Applications (BLAs) or New Drug Applications (NDAs), Marketing Authorization Applications (MAA), Investigational New Drug Applications (INDs), and Clinical Trial Applications (CTAs).
- Demonstrate an excellent understanding of FDA and international regulatory requirements.
- Must have experience working with FDA locally and nationally.
- Strong writing, project management and communication skills
- Proven ability to develop and manage staff

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.

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

Qualified candidates may submit **resumes** to careers@vitaltherapies.com