VITAL THERAPIES®
TARGETING LIVER DISEASE

Director, Regulatory Affairs – Device

We are currently seeking a **Director of Regulatory Affairs – Device** to focus on directing our device team in meeting medical device requirements in the US and Europe for both clinical trials and commercialization of the product, a combination biologic/device in Phase 3 development.

The **Director of Regulatory Affairs – Device** will identify, review, and anticipate emerging regulatory device issues. The Director will perform a gap analysis and ensure all applicable device regulations are met by the current product. The Director will develop and implement regulatory strategies and guidance based on U.S. and international requirements as defined in FDA Regulations for combination products, ISO 13485:2003 Standard, European Medical Device Directives and other pertinent International Regulations. This role also will establish effective dialogue with U.S. and international regulatory authorities, direct the planning and preparation of device regulatory submissions for the company's product, and facilitate timely product registrations and regulatory approvals.

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

- Oversee the update and maintenance of the device history file, technical file, and other international registrations;
- Evaluate device change controls;
- Establish and execute regulatory strategies for new product development providing direction on the interpretation and application of regulations and guidance related to devices and combination products;
- Ensure device regulatory strategy is in alignment with commercial strategy and the Target Product Profile (TPP);
- Provide oversight in taking innovative ideas from proof of concept through regulatory strategy, including product development, manufacturing, filing and approval, and commercial operations;
- Execute regulatory functions such as planning and filing of documentation with U.S. and international regulatory agencies;
- Obtain/generate information to be submitted to regulatory authorities and prepare required regulatory submissions;
- Function as a Subject Matter Expert in device related discussions with Health Authorities;
- Collaborate with the Quality organization in driving compliance activities related to FDA and ISO regulations, and quality system standards activities;
- Carry out data integrity review for device-related documents prior to submission;
- Lead relevant project planning and review meetings;
- Identify and ensure the establishment and monitoring of a submission tracker for device documentation.

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

- Ensure timely review of device documentation, and protocols and reports. Prepare additional written materials as needed;
- Prepare device-related responses to FDA letters, supplements, and amendments;
- Participate in FDA inspections and preparation as required;
- Write pertinent regulatory SOP's and develop and implement training programs for direct reports and other functional groups to assure awareness and compliance of all device requirements;
- Participate in the preparation of the department's budget; ensure that the department operates within capital and expense budget guidelines;
- Monitor the US and international medical device-related regulatory environments, and provide executive management with assessments of the impact of new and changing regulations;
- Participate in medical device-related recalls in collaboration with CMOs as necessary;
- Review product complaints for reporting as required by relevant agencies; and
- Perform all other related duties as directed by management.

Position Requirements:

Education and Experience:

- Ph.D. with 4 to six years related experience; Masters degree with 7 to 9 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 complex medical devices. Ideally this should be combined with experience in filing new market applications for drug or biologic products, and even more ideally including combination products and ATMPs. Degree preferably in science or other technically related field or equivalent
- Experience working with FDA, EMA and MHLW, and ideally other regulatory authorities worldwide
- Proven ability to prepare and submit documents to FDA, such as 510(k), Premarket Notifications, Investigational Device Exemptions (IDEs), Premarket Approval Applications, (PMAs), Investigational New Drug submissions (INDs), or Biologics License Application (BLA)
- Strong knowledge of ISO and QSR requirements and execution
- Experience in Bill of Materials (BOM) lifecycle management
- An excellent understanding of FDA and international regulatory requirements
- A team player with experience working with CMOs and suppliers
- Strong writing, project management and communication skills

Position Requirements (Cont.):

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.