VITAL THERAPIES®
TARGETING LIVER DISEASE

POSITION DESCRIPTION

Title: Director, Regulatory Affairs - CMC

Date Effective: August, 2014

Department: Regulatory & Quality

Reports To: Senior Director, Regulatory Affairs

Position Overview:

The Director of Regulatory Affairs – CMC will identify, review and anticipate emerging regulatory issues related to product quality and controls for the product lifecycle. The Director will develop and implement regulatory strategies and guidance based on U.S. and International requirements as defined in FDA Regulations, ISO 13485:2003 Standard, European Human Medicines Regulations and European Medical Device Directives, Canadian Drug and Medical Device Regulations, Australian Therapeutic Goods Medicines and Medical Devices Regulations and other International Regulations. This role also will establish effective dialogue with U.S. and International regulatory authorities, direct the planning and preparation of CMC-focused regulatory submissions for the company's products and facilitate timely product registrations and regulatory approvals.

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

- Establishing and executing a Regulatory strategy for 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
- Lead/manage complex CMC projects requiring coordination of cross-functional resources and strategic management of competing priorities that have a direct impact on site operation
- Provide input and review of global biologic and device regulatory CMC requirements and project risk assessments
- Represent (and lead, if applicable) Regulatory CMC department in global Agency meetings
- Prioritize, develop, and prepare submissions and facilitate Agency approval
- Manage resources for CMC submission preparation and communication with internal/external customers to achieve all phases of product approval and commercialization of products
- Provide mentoring and developmental coaching to Regulatory staff
- Participate in project teams to manage regulatory CMC related activities and/or changes related to product development, manufacturing, and commercialization
- Provide review of and input of regulatory CMC aspects of product development plans
- Coach others on technical and scientific aspects of regulatory CMC issues and submissions
- Facilitate sharing of critical research and development information

- When appropriate, provide strategic regulatory CMC guidance for problems being discussed and recommend solutions.
- Identify and drive continuous improvement in support of quality standards and business results
- Guides and coaches others in the appropriate application of regulations and standards related to submission preparation and commercialization, product and labeling compliance
- Collaborate with Quality Assurance to manage programs and ensure regulatory compliance during product development, validation, and commercialization activities subject to regulations established by US, EMA, and other relevant global health agencies.
- Interact with outside consulting groups and manage activities necessary for completing key initiatives
- 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, Design Dossiers, Technical Files, INDs, NDAs, BLAs and other International Registrations
- Preparing responses to FDA letters, supplements, and amendments; participates in FDA inspections and presentations as required
- Writing Divisional SOPs and develops and implements training programs for direct reports and other functional groups to assure awareness of all requirements and maintain compliance with all current regulation
- Performing all other related duties as directed by management

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Position Requirements:

Education and Experience:

- Ph.D. with 4 to six years related experience; Master's 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 device AND drug or biologic products. Degree preferably in science or other technically related field or equivalent.
- Proven ability to prepare and submit documents to FDA, such as 510(k) Premarket Notifications, Investigational Device Exemptions (IDEs), and Premarket Approval Applications, (PMAs), Investigational New Drug (IND), New Drug Applications (NDA) or Biologics License Applications (BLAs).

- 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

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.