St. Renatus

Regulatory Affairs Director

St. Renatus is a Fort Collins, Colorado based company that was founded to develop a revolutionary innovation – the world's first dental anesthetic administered through the nasal cavity. Having just completed our U.S. Food and Drug Administration (FDA) Phase 3 Clinical Trials, the company anticipates moving into a period of organizational growth and activity. We are seeking a talented Regulatory Affairs Director responsible for further development and execution of regulatory strategies in support of ongoing business operations with an emphasis on ensuring compliance to St. Renatus' Quality System and all applicable domestic and international regulations and standards. The incumbent is also responsible for directing the Regulatory function, overseeing CMC document preparation, content review and submissions to ensure high quality and timely submissions to regulatory agencies. This position will also support regulatory operations in the European Union and throughout the world.

Job Responsibilities

- Provide strategic advice and counsel to Senior Management regarding regulatory requirements.
- Contribute to cross functional project teams and provide Regulatory input for projects.
- Manage regulatory department to ensure all reports are compiled monthly, quarterly & annually. Direct the preparation and quality check of all regulatory filings.
- Prepare compliant, complex regulatory submissions required for maintenance of INDs and NDAs, such as adverse event reports, pre- and post-approval amendments, annual reports, and drug advertising.
- Manage promotion and labeling aspects of new drugs.
- Review and edit source documents and summary documents prepared by others for completeness and regulatory compliance.
- Coordinate communications with FDA, EMEA, and other global health authorities including emails, face-to-face meetings, and teleconferences.
- Coordinate regulatory submissions for NDAs, ANDAs, and INDs to regulatory agencies.
- Direct CMC regulatory activities for the current projects, including INDs, DMFs, NDA, MAA, IMPDs, ASMFs.
- Take the initiative to provide CMC gap analyses from a Regulatory perspective.
- Support other regulatory tasks (clinical and non-clinical), on a needed basis. This could include: Compilation of submissions and submission components (investigational and marketing); Review of submissions to ensure that it meets global regulatory requirements and current industry standards; Regulatory intelligence guidance, if needed.
- Develop and deliver necessary training and participate in training and development of junior staff.
- Participate as member of the Management Team in planning to achieve site goals and objectives; communicate and help resolve issues or problems that have interdepartmental impacts and in planning to enhance and expand the opportunities.
- Determine necessary headcount within Regulatory area to ensure delivery against goals.
- Manage non-exempt, exempt and/or supervisory level personnel as the company grows.

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Education / Experience

- Minimum of a BS or BA degree in a life science or natural science, graduate degree preferred.
- Experience in the Pharmaceutical industry with at least 10 years of proven Regulatory Affairs experience is required.
- Proven track record of successfully managing the Regulatory process throughout the lifecycle of a pharmaceutical product.
- Solid working knowledge of current FDA and EMA regulations and guidelines.
- Thorough understanding of contract manufacturing in the Pharmaceutical industry.
- Experience with documentation systems and e-publishing systems is preferred.
- Experience with manufacture of anesthetics is preferred.
- Management experience is preferred.

Essential Physical Requirements

Work environment is office based with some travel. Ability to effectively utilize computer equipment. This position is predominately sedentary but may be required to travel, stand, walk, use hands to finger, handle, or feel, and reach with hands and arms. The ability to hear normal conversation, see documents and computer screens, and talk, are all essential physical requirements.

Date modified 10/27/15

If you meet the minimum education & experience requirements and want to be considered for the position, please attach a current resume and cover letter connecting your experience to the posting and send to recruiting@st-renatus.com.