Associate Director/Director, Regulatory Affairs Submissions and Operations

Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational therapy Haduvio™ (oral nalbuphine ER) for patients with chronic cough in idiopathic pulmonary fibrosis (IPF) and refractory chronic cough (RCC). The IPF program is in a Phase 2b study and RCC is in a Phase 2a study. Both studies are expected to read out over the next 12 months. Haduvio is a dual κ-opioid receptor agonist / μ-opioid receptor antagonist that works both centrally in the brain as well as peripherally in the lungs and has the potential for a synergistic antitussive effect to treat chronic cough. Parenteral nalbuphine is not scheduled by the U.S. Drug Enforcement Agency.

Position Summary:

This role reports to the Senior Director of Global Regulatory Affairs with the primary objective to execute and pull through regulatory strategy and guidance, ensuring a fully compliant and successful outcome for the company and partners. Selected candidate must have a working knowledge of global regulations, submission practices and requirements with proven attentiveness to detail to translate the company regulatory strategy into compliant submissions and best practices.

The role is accountable for three main areas:
1. Regulatory submission planning, prioritization, execution and successful delivery to health authorities.
2. Various Operational aspects of regulatory submissions including document management.
3. Support for Regulatory Strategy including providing input on the regulatory development plan.

The incumbent will work in a close cross-functional partnership with all functions within Trevi Therapeutics, Inc. as well as with Contract Research Organizations, alliance partners and vendors performing work on behalf of Trevi.

Duties and Responsibilities:

Regulatory Operations

- Serves as a subject matter expert on US and global regulatory matters (i.e. global regulations, current guidance and changes, electronic submissions and platforms)
- Identifies compliance issues to Regulatory management to facilitate remediation and continuous improvement with the appropriate stakeholders
- Maintains awareness of Regulatory Health Authority Policy, trends, and changes that could impact the submission space (ICH, electronic requirements, submission content.)
- Provides oversight and guidance for regulatory documents and dossiers in accordance with company policies and SOPs
- Implements and organizes/manages an Electronic Document Management platform to establish taxonomy, naming conventions, version control and audit trail maintenance including monitoring 21CFR Part 11 Compliance
- Provides regulatory operational documentation support for submission components to ensure documents comply with electronic guidance
- Ensure all regulatory authors have training and access to the appropriate authoring templates and shared drive(s)

Regulatory Submission Management

- Develops and enforces company submission standards and best practices. Provides oversight on routine regulatory submissions, such as those for IND safety reports, clinical site documentation updates (1572s), lot releases, promotional pieces and protocol amendments
- Provides regulatory project management for submission deliverables such as INDs and IND amendments, CTAs and amendments, NDAs, BLAs and amendments/supplements, MAAs and Variations in accordance with applicable Regulatory Agency regulations, guidelines, and/or specifications (eg, FDA, EMA, ICH, etc).
- Provides guidance to development team to ensure that company timelines embed requirements that are dictated by regulatory guidance
- Facilitates cross functional regulatory teams (internal staff and external CROs and partners) to develop regulatory submission content plans and execute them. Leads and guides participants in critical thinking along with decision-making criteria to ensure content quality optimization and speed towards submissions.
- Serves as a contact with submission publishing vendors
- Provides regulatory review of draft documentation and submissions (including for potential to outsource activities to third party companies (under special agreement arrangements)
- Submits new INDs including potential administrative splits for FDA Divisions to facilitate development plans
- Maintains existing INDs (Investigator updates, annual reporting, safety reporting, etc.)
- Submits updates to CMC sections by working with the manufacturing group or consultants
- Submits meeting requests to the US FDA and equivalent to other agencies as needed.
- Drafts and submits submissions such as orphan drug, breakthrough therapy and fast track applications
- Contributes to other submission activities, such as Development Safety Update Reports (DSUR)
- Coordinates and manages marketing application (NDA, BLA, MAA) planning and submission
- Improves operational effectiveness to increase the efficiency of procedures, processes and systems while increasing awareness of standards and compliance with regulations and law
- Integrates future submission needs into the early development program (CMC, Nonclinical, Clinical)

Vendor/Partner Management

- Provides vendor oversight/communication of company expectations and standards
- Oversees CTA process outside the US with CROs and Vendors
- Supports the regulatory aspects of partnerships in foreign countries
- Acts as the point of contact for CROs and partners to provide documents/dossiers and communicate on regulatory questions

Other responsibilities

- Draft, track and submit export certification documentation for ex-US countries requiring Export Certifications

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skills, and/or abilities required.

Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and Experience:

- BS, MS or PhD in a scientific field
- 10-15 years of Regulatory Experience
- Global Regulatory Submission Management experience including INDs, NDAs, CTAs
- Familiarity with ICH and Global Health Authority regulation and guidance which governs investigational drug development and marketing applications
- Experience reviewing and writing Standard Operating Procedures

Competencies:

- Able to read, comprehend, write, and speak English fluently
- Collaboration with external vendors and CROs
- Excellent written and verbal communication and interpersonal skills. Able to communicate complex information clearly and succinctly, both in writing and orally
- Proficient in Microsoft Office (Word, Excel, PowerPoint, Outlook), SharePoint, Box, Adobe Pro
- Must be highly detail-oriented and have strong organizational and time management skills. Ability to multi-task, manage and prioritize various and differing projects, as well as work effectively toward numerous deadlines

PHYSICAL AND VISUAL REQUIREMENTS:

This position requires the individual to maintain a professional appearance as they are greeting all guests. While performing the duties of this job, the individual is regularly required to use computers and office equipment, manipulate documents, and work in an office environment and work remotely from home as needed. The individual will experience prolonged periods of sitting and will also be required to talk or hear, reach with hands and arms, walk, bend, and stand frequently and may occasionally move materials up to 15 pounds. 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.

Note:

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Trevi reserves the right to modify, change or add to the position's job duties and responsibilities as business needs may require. This document does not create an employment contract, implied or otherwise, other than an "at will" relationship.

Trevi Therapeutics, Inc. is an Equal Opportunity/Affirmative Action employer including protected Veterans and individuals with disabilities. Trevi considers applicants for employment without regard to, and does not discriminate on the basis of, an individual's sex, race, color, religion, age, disability, status as a veteran, or national or ethnic origin; nor does Trevi discriminate on the basis of sexual orientation or gender identity or expression.