Regulatory Affairs Internship

Position Summary

The primary objective is to support the Regulatory Affairs Department in the execution of the Company's Regulatory Strategy by assisting in Operational activities to ensure fully compliant Health Authority submissions. The selected candidate should be pursuing a major in a scientific field, have attentiveness to detail, good computer skills, and excellent written and oral communication skills. The goal is to help the intern develop a working knowledge of drug development, the applicable Global Regulations and Guidances, and document/Health Authority submission management.

This is a paid, 20-40 hours per week position with a hybrid schedule consisting of 3 days in-person and 2 days of working remotely in New Haven, CT. This position reports directly to the Senior Director of Regulatory Affairs.

Principal Responsibilities

Key responsibilities of this role include, but are not limited to:

- Document management, including ensuring regulatory documentation conforms to global health authority standards
- Evaluation of clinical trial materials for compliance with future regulatory requirements
- Review of internal company regulatory documentation for accuracy and compliance
- Preparation or review of company regulatory procedures (SOPs, Work Instructions, etc.)
- Assist with vendor management for regulatory submissions
- Assist with timelines and tracking for regulatory submissions

Qualifications

- Intermediate computer software skills with MS Office (Word, Excel, Outlook, PowerPoint)
- Excellent organizational skills and an ability to prioritize effectively to deliver results within reasonably established timelines
- Ability to work independently and as part of a team
- Strong interpersonal skills including verbal and written communication are essential in this collaborative work environment

Education

- High school or equivalent (Preferred)
- Currently enrolled full-time in an undergraduate program. Candidate must be pursuing a degree in Regulatory Affairs, Biology, Chemistry, Pharmacy, or a related field

Trevi Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing the investigational oral therapy Haduvio™ (nalbuphine ER) for the treatment of chronic cough in adults with idiopathic pulmonary fibrosis (IPF), other chronic cough indications, and for the treatment of prurigo nodularis. The Company reported statistically significant results from the Phase 2 CANAL trial of Haduvio for the treatment of chronic cough in adults with idiopathic pulmonary fibrosis (IPF). Based on this positive data, Trevi plans to focus future clinical development on chronic cough conditions, including IPF, refractory chronic cough, and interstitial lung diseases (ILDs).