Head of Regulatory Affairs

Background

Proteon Therapeutics is a biopharmaceutical company focused on the discovery and development of innovative treatments for vascular and kidney diseases. Proteon's lead drug is vonapanitase, a recombinant human elastase, currently in phase 3 clinical trials for hemodialysis access and in phase 1 studies for peripheral artery disease (PAD).

Position Summary

The Head of Regulatory Affairs will be responsible for all aspects of the Regulatory at Proteon Therapeutics, Inc. The Head of Regulatory Affairs will develop a Regulatory development strategy, advise management on Regulatory risk and lead interactions with Regulatory agencies on behalf of the company.

This position involves both high level strategic planning as well as hands-on responsibilities. This position reports to the Chief Medical Officer.

Regulatory Leadership

- Develop US and global regulatory strategy aligned with business objectives
- Provide guidance, direction and leadership on that strategy to the development team and senior management
- Make strategic contributions to clinical development plans
- Maintain up-to-date knowledge of US laws, regulations and guidelines as well as familiarity with the global regulatory environment
- Act as primary liaison with all regulatory authorities via regulatory correspondence and leading regulatory meetings
- Identify and coordinate with regulatory experts and consultants
- Hire and develop supporting regulatory staff
- Ensure operations are compliant with FDA, ICH, EMA and industry standards
- Develop and maintain department budget

Regulatory Submissions

- Maintain all global regulatory applications
- Author, review and edit regulatory submissions
- Provide project plans and timelines for regulatory submissions
- Drive timelines and deliverables related to submission documents
- Ensure QC checks of pending submissions
- Understand electronic submission process and guide the development team in the preparation of electronic regulatory submissions
- Manage CROs responsible for electronic submissions

Regulatory Documentation

- Author, review and/or edit documents i.e., informed consents, Investigator's Brochures, study materials, essential documents, presentations, and reports as necessary

Ideal Qualifications

- Advance degree with minimum of 15 years industry experience and 8-10 years of direct regulatory experience and 5 years' experience in a senior regulatory role
- Excellent working knowledge of drug development process and knowledge of FDA regulatory requirements
- EU and global regulatory experience
- NDA/BLA and MAA experience
- Ability to lead collaborative teams
- Strong strategic and analytical abilities
- Electronic submission experience
- Demonstrated leadership competencies in establishing clear direction and objectives; ability to simplify complex processes and foster an environment that brings out the best in people
- Excellent verbal and written communication skills
- Ability to provide strong regulatory leadership on a cross-functional team
- Advanced knowledge and experience in interpretation of regulations, guidelines and precedents related to drug development
- Experience with orphan indications, fast track development products, and biologics a plus