Project Manager, Regulatory Affairs Operations

Do you want to be part of building a fully integrated biopharmaceutical company together with a team of highly skilled colleagues who are passionate about developing best-in-class therapeutics that address significant unmet medical needs? Then Ascendis Pharma is committed to support your personal development on our journey towards becoming a leading rare disease company.

Ascendis Pharma is looking to hire an experienced Project Manager, Regulatory Affairs Operations to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The Project Manager, Regulatory Affairs Operations will play a critical role in Ascendis' success in facilitating the submissions of the license application for our lead product, TransCon hGH, by tracking and shepherding the progress of contributions to the regulatory filing. He/she will be responsible for establishing a comprehensive project plan, engaging all contributors, reviewers, and other stakeholders, and driving on-time execution. This Project Manager, Regulatory Affairs Operations position is based in Palo Alto, and will report to the Director, Regulatory Operations.

Key Responsibilities

- Coordinate preparation of Clinical sections of BLA for our lead candidate, TransCon hGH. The documents will be prepared by our Clinical team based in Palo Alto, under the leadership of the Senior Medical Director, Clinical Development and the Chief Medical Officer. The Project Manager will also work closely with our colleagues in the Strategic Planning & Project Management and Product Development groups.
    - Create a project plan to compile all components of the BLA filing: define the process, timelines, owners, reviewers, and interdependencies of these components.
    - Follow-up with owners and reviewers to ensure on-time execution.
    - Define critical path and at-risk activities, anticipate bottlenecks, and clear barriers to progress.
- Drive a gap analysis of BLA-enabling activities, with a focus on Clinical. In this role, you will be responsible for identifying and agreeing on additional work to be performed, gaps in owner/writer and reviewer roles and/or capabilities, and you will propose options for solutions.
- Communicate progress and risks to Clinical team, TransCon hGH Core Team, and Senior Management.
- Collaborate closely with the Preclinical, Bioanalysis, and Product Development departments, all of which will make significant contributions to the BLA filing also.
- Build project plans for other regulatory filings (e.g. in other global regions, for other indications, and on other products).
- Share best practices and learnings with other stakeholders.

Knowledge, Skills and Experience

- Experience with BLA/NDA submissions to FDA
- BA/BS degree required; advanced degree preferred
- 5+ years in project management in R&D drug development
- Pharmaceutical R&D drug development knowledge
- Direct experience in, or collaborative partnership with multiple functions e.g., Clinical Development, Clinical Operations, Regulatory Affairs, Medical/Regulatory Writing
- PMP certification preferred
- Exceptional interpersonal skills (including cultural sensitivity) and assertive-yet-diplomatic communication skills (including presentations, written communications)
- Strong leadership skills, including ability to lead colleagues across line organizations outside of reporting relationships
- High level of organizational skills and attention to detail
- Ability to travel up to 10% of the time domestically and internationally

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Project Manager, Regulatory Affairs Operations" in the subject field.