Vice President, Regulatory Affairs

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 a Vice President, Regulatory Affairs to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position, Location and Scope

The Vice President, Regulatory Affairs will be a key member of the project leadership teams and will help to inform the design and execution of clinical trials, as well as manage all regulatory submissions for the company. This individual will direct and coordinate activities in regulatory and work with the executive team in formulating strategy, enhancing performance, and administering relevant policies around this critical functional area. S/he will provide strategic leadership and key insights that will allow the organization to operate collaboratively and proactively, interacting closely with internal peers and externally with FDA, EMA, and other key stakeholders.

S/he must not only be adept at formulating and driving strategy, but also be tactically oriented, preparing and writing submissions and playing a hands-on role in regulatory submissions. Furthermore, this individual will have demonstrated an ability to partner effectively with multiple functions, including Clinical, Research, Development, Medical Affairs and Quality. At a personal level, the company is seeking a highly motivated individual who thrives on being challenged and working in highly collaborative environments to contribute to their cutting-edge science. Strong interpersonal skills are necessary, as this individual will serve as a voice for the company internally as a trusted member of the team. A proven ability to communicate with other members of the executive management team, Board members, external thought leaders, and research and development staff in a fast-paced environment is crucial. Furthermore, the capacity for strategic thinking is highly important. In short, outstanding leadership and management skills with rigorous scientific intellect and standards, and understanding of the business aspects of drug development are required. Finally, an ability to think and manage strategically, with an attention to detail is needed, as is a high energy level, focus, and a passion and sense of urgency for developing important new medicines for devastating diseases.

This position will report to the company's Chief Medical Officer and ideally be based in the Ascendis Pharma corporate offices in Palo Alto, CA.

Specific Responsibilities

- Collaborate with Clinical to develop and implement the US and global regulatory affairs plan across products

- Oversee development and refinement of regulatory policies and procedures and SOPs
- Work closely with commercial, clinical development and Medical Affairs in designing and implementing launch strategies and tactics, and life cycle planning
- Provide regulatory assessments of product opportunities and threats
- Develop strategic imperatives and tactical plans to enhance healthcare practitioner education to improve patient outcomes
- Provide regulatory expertise in the development and approval of promotional materials
- Collaborate with Commercial, Legal, and Clinical for development and review of labeling, advertising and promotional materials
- Monitor the competitive environment to sustain expertise in therapeutic area treatment management and new therapies, competitive products and features
- Lead, develop, mentor and manage the Regulatory Affairs team

Position Requirements & Experience

- 15 years or more of regulatory experience in a biopharmaceutical company developing proteins and peptides, or alternatively, small molecule therapeutics
- Preferred candidates will have a broad blend of experience in Regulatory Affairs and have worked directly with FDA and other international agencies on clinical and regulatory matters
- An advanced degree such as PhD, MD, MD/PhD or other relevant advanced degree preferred
- Must have a proven success track record of developing short- and long-term regulatory affairs and clinical strategies to deliver innovative medicines to the market
- Recent filing experience globally, U.S. and European regulatory authorities required, experience with Asia / Pacific region a plus
- Deep familiarity with the overall drug development process especially related to clinical trial requirements for submissions required
- Biologics, CMC and toxicology experience
- Experience with Orphan Drugs development and fast track regulatory processes
- Experience with BLA/NDA filing a must; experience with other filings highly desirable- IND filings, PSPs, PIPs, orphan and breakthrough product applications.
- Familiarity with combination products of drug-device is a plus
- Strong leadership experience and capabilities are essential
    - Previous mentorship experience of junior regulatory staff
    - Proven ability to lead and manage regulatory team from a distance (joint locations)
    - Leadership polish and gravitas
- Previous successful experience leading / participating in FDA / EMEA or other regulatory meetings
- Excellent writing, communication, and presentation skills
- Ability to travel internationally up to 20% of the time

Personal Characteristics & Cultural Fit

- Highly motivated individual who thrives on working in collaborative environments
- Team player and highly collaborative with executive team, colleagues, investigators, and clinical research partners
- Strong cultural sensitivity and ability to lead / manage from a distance
- Ability to follow complex direction/processes under pressure
- Proficient balancing multiple routine tasks simultaneously to achieve goals
- Very strong organizational skills, with attention to detail.
- Works well under general direction, with ability to independently determine and develop approaches to non-routine problems – a self-starter

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