Senior Director, 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 hire a passionate Senior Director, Regulatory Affairs who will report to the Vice President, Regulatory Affairs and will be responsible for execution of all regulatory activities within assigned area the organization. This is an exciting opportunity to join a rapidly growing, innovative company!

Mains areas of responsibility:

- Responsible for Regulatory global submissions in terms of strategic advice /decisions, coordination, and leading the team efforts to result in on time submissions
- Company expert on regulations both FDA and EMEA
- Represents the company to regulatory authorities
- Proactively identifies constraints or possible risks to programs in terms of regulations
- Stays abreast of current regulations and competitive intelligence
- Mentors department personnel and updates appropriate departments on the current regulatory environment
- Mentors or manages others as assigned
- Must be hands-on for project team requirements
- Serve as the regulatory project team lead for a designated project and as such would be responsible for the production of all major US and EU filings

Requirements:

- 15 years or more of regulatory experience in a pharmaceutical company.
- Minimum of Bachelors' degree
- Experience with U.S. and European regulatory authorities required. Experience with Japan a plus.
- Deep familiarity with the overall drug development process especially related to clinical trial requirements for submissions required
- Biologics experience preferred.
- 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
- Previous mentorship experience of more junior regulatory staff
- Previous experience participating in FDA / EMEA or other regulatory meetings
- Good writing, communication, and presentation skills
- Ability to travel internationally up to 20% of the time
- Experience in Asia/pacific sector (i.e., Japan and Korea a plus)

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative prodrug technology to build a leading, fully integrated rare disease company focused on making a meaningful difference in patients' lives. The company utilizes its TransCon technology with clinically validated parent drugs to create new therapies with potential for best-in-class efficacy, safety and/or convenience.

Ascendis Pharma has a wholly-owned pipeline of three rare disease endocrinology product candidates in clinical development. These include once-weekly TransCon Growth Hormone, which is being evaluated in a phase 3 program for children with growth hormone deficiency (GHD), TransCon PTH, a long-acting prodrug of parathyroid hormone for hypoparathyroidism for which a phase 1 trial has been completed, and TransCon CNP, a long-acting prodrug of C-type natriuretic peptide, which is also in phase 1 development for achondroplasia and other FGFR-related skeletal disorders.

Additionally, Ascendis Pharma has multi-product collaborations with Sanofi in diabetes and Genentech in the field of ophthalmology.

For more information, please visit www.ascendispharma.com.