Senior Director, Regulatory Affairs

You will be a key person in the company's first BLA filing

Ascendis Pharma is an entrepreneurial and fast-growing company where skilled, agile and highly resourceful professionals can truly make their mark. Ascendis offers a dynamic place for employees to grow and develop their skills, while influencing the direction of this global company.

As Senior Director, Regulatory Affairs you will be a key member of the Regulatory Affairs team and the Regulatory Affairs management team. You will be Lead for the Regulatory Affairs team for TransCon hGH and work closely with stakeholders in all functions which includes a very close working relationship to the TransCon hGH Project Director. Your efforts will be the key to a successful BLA submission of the TransCon hGH BLA but you will also be supporting other activities for TransCon hGH.

With direct report to the Vice President, Regulatory Affairs.

Your main tasks are:

- Provide high level strategic and operational regulatory direction and mentorship on projects while acting as Team Lead for part of the team
- R&D focused project management for late stage global regulatory filings
- Establish and maintain real-time filing timelines, and track deliverables for components or modules of major submissions from filing through registration
- Lead, attend and contribute to critical Filing team and sub-team meetings – help manage and follow-through on project deliverables and outstanding action items between Nonclinical, CMC, Clinical and Regulatory sub-teams
- Coordinate updating of project dashboards and status updates and reports for sharing progress and risks with Filing team, subteams, and senior management team (periodically)
- Schedule and coordinate reviews and roundtables as needed per the filing timelines
- Contribute to planning and support for cross-functional workshops focused on execution of submission strategy
- Contribute to development of best practices and standardized process for filing of regulatory submissions, e.g., TransCon hGH BLA
- Co-lead BLA sub-teams (e.g., CMC, Preclinical, Clinical) with functional expert
- Contribute to internal regulatory policies and procedures to achieve best practices and work processes by writing SOPs
- Support the company through regulatory intelligence efforts by staying abreast of newly issued regulatory laws, guidance and technical publications
- Support other regulatory activities for TransCon hGH

Your qualifications include as a minimum 10 years of documented professional experience from a Regulatory Affairs position from a pharmaceutical/biotechnology company developing biologics or synthetic peptides. You must have extensive regulatory experience including

IND/CTA, NDA/BLA/MAA, lifecycle management, labelling, interactions with Health Authorities, and experience in developing short- and long-term regulatory strategies to rapidly deliver innovative products to the market. Finally, the candidate must have demonstrated an ability to collaborate effectively with multiple functions, including Research, Development, Clinical, Commercial, and Quality.

You have a relevant Master's Degree within Life Science and you have experience working as a RA project lead of BLA and/or NDA filings. Further, you have a strong understanding of clinical development and how to present clinical data to FDA. In addition, you must have experience with labelling development and with the close collaboration with marketing and market access. Preferably, you have experience in working with a combination product.

You are a person who thrives on being challenged and working in collaborative environments. Strong interpersonal skills are necessary, as you will serve as a major contributor and trusted member of the project development teams. A proven ability to communicate with other development staff in a fast-paced environment is crucial. Finally, an ability to think and manage strategically with 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.

Ascendis Pharma offers you an exciting and challenging position in an entrepreneurial and international company with a short line of command. You will be involved in activities that are central to Ascendis Pharma's strategy and work with highly skilled and experienced colleagues to advance their exciting product pipeline and get the first product on the market.

Travelling: 30-40 days per year.

Domicile: Ascendis Pharma resides in a wonderful office facility in Tuborg Havn in Hellerup with a view of the harbor, the canals and the sea.

For more details about the job or the company, please contact Research Consultant, Jeanne Dederding, Unique Human Capital on M: +45 28 74 58 71. All applications must be in English and are treated confidentially.

Click here to APPLY.

Ascendis Pharma is an entrepreneurial and fast-growing company where skilled, agile and highly resourceful professionals can truly make their mark. Ascendis offers a dynamic place for employees to grow and develop their skills, while influencing the direction of this global company. Ascendis Pharma is in the process of expanding its pipeline with more drug candidates and is putting considerable emphasis on the further clinical development of its own products.