Vice President, Regulatory Affairs

Great opportunity to influence the regulatory strategy of a fast-growing biotech company

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.

The position of Vice President, Regulatory Affairs at Ascendis Pharma is a once in a lifetime opportunity to be part of setting up the structure and function of the Global Regulatory Affairs and to lead the company's first BLA submission.

In this role, you will be responsible for setting the long-term strategy and vision for the regulatory function, creating and executing regulatory strategies, and collaborating with Ascendis' leadership to set goals, drive process efficiencies and overall operational effectiveness for global regulatory submissions.

Reporting to the Chief Executive Officer, the candidate will leverage broad knowledge and expertise to lead key cross-functional initiatives and global filings. The candidate will take a company-wide approach to problem solving and provide Ascendis colleagues with the information and innovative tools required to prepare successful and high-quality regulatory submissions, creating a seamless environment for all stakeholders.

Your main tasks are:

- Responsibility for the Global Regulatory Affairs organization across DK and US
- Lead the regulatory function and enable successful product development, approvals and life-cycle management.

- Establish the long-term strategy for the regulatory team, activities and planning in accordance with an established road-map and with an expectation to scale-up efficiently and rapidly.
- Provide strong cross-functional leadership for global filings, and support the growth of the regulatory department.
- Build and maintain strong leadership capabilities at all levels within the regulatory team and support the professional development of regulatory team members.
- Ensure the successful on time delivery of high-quality submissions to global regulatory health authorities in alignment with both Ascendis and health authority standards.
- Oversee the development and implementation of innovative systems, tools and streamlined processes to create and maintain high-quality regulatory submissions and manage a state-of-the-art regulatory intelligence and knowledge management approach.

- Responsibility for continuous improvement of systems and processes, including internal training, for the Regulatory department and cross-functional teams.
- Ensure inspection readiness efforts for regulatory activities and files
- Manage Regulatory budgets and vendors
- Maintain current expertise in regulatory trends and operations
- Participate as needed in technical discussions and collaborate with corresponding groups at Health Authorities

Your qualifications are +10 years of documented professional accomplishment and at least 10 years of documented experience from a Regulatory Affairs SVP/VP position in the pharma/biotech industry. Experience with the submission of BLA/NDA/MAA is a must. Moreover, you have extensive regulatory experience including IND/CTA, lifecycle management, and interactions with Health Authorities. You have developed and implemented complex regulatory strategies and you have a proven track record of significant regulatory accomplishment. Moreover, you have the proven ability to drive results and work successfully within a cross-functional team/partnership environment with a high level of professionalism. Finally, you have experience in interacting with external business parterns and Regulatory Agencies.

You have a Master's Degree within the Natural Sciences or a related field.

You are a person with the ability to analyze, define and effectively convey difficult and complex issues in a way that accurately and persuasively communicates the issues to both internal and external stakeholders. Extensive manegerial experience from a global RA position is required.

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 Ascendis Pharma's exciting product pipeline.

Travelling: You must be able to travel minimum 1 week per month.

Place of work: This position can work either from the office in Copenhagen, Denmark or in Palo Alto in the USA.

For more details about the job or the company, please contact Partner Jørn Duhn, Unique Human Capital on M +45 21 75 19 25. All applications must be in English and are treated confidentially.

Click here to APPLY.

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