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 an experienced Senior Director, Regulatory Affairs to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

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 focused on the development of global strategies and be one of the key leaders contributing to the overall Regulatory Affairs Strategy involving our oncology programs. This position will work closely with stakeholders in all functions, including a very close working relationship to the Regulatory group in our Copenhagen office and Project Directors. Currently we have several pre-clinical programs and your efforts will be instrumental to a successful IND submission next year. You will also be supporting other activities related to development of our oncology portfolio. The Senior Director, Regulatory Affairs will directly report to the Vice President, Global Regulatory Affairs and will be based in Palo Alto, California. The Senior Director will also be responsible to help build a Regulatory group to support future oncology programs.

Key Responsibilities

- Provide high level strategic and operational regulatory direction and mentorship on clinical development programs in oncology
- R&D focused Regulatory 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
- 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, sub-teams, and senior management team (periodically)
- Schedule and coordinate reviews and roundtables as needed per the regional 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
- Co-lead relevant 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 the oncology portfolio

Knowledge, Skills and Experience

- Master's degree within Life Science and experience working as a RA project lead of BLA and/or NDA filings
- Minimum 10 years of documented professional experience at a Regulatory Affairs position from a pharmaceutical/biotechnology company developing biologics, small molecules, or synthetic peptides
- Have a strong understanding of clinical development and how to present clinical data to FDA
- Experience with labeling development and in close collaboration with marketing and market access departments.
- Experience working with a drug device combination product preferred
- Extensive regulatory experience including IND/CTA, NDA/BLA/MAA, lifecycle management, labeling, interactions with Health Authorities, and experience in developing short- and long-term regulatory strategies to rapidly deliver innovative products to the market
- Demonstrated an ability to collaborate effectively with multiple functions, including Research, Development, Clinical, Commercial, and Quality
- Ability to travel up to 30-40 days per year domestically and internationally

Want to apply? Please send your resume to US_jobs@ascendispharma.com. Please write "Senior Director, Regulatory Affairs - Oncology" in the subject field.