Director Regulatory Affairs (CMC)

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. A late stage project is also moving towards marketing registration and commercialization.

It is a once in a lifetime opportunity to be part of setting up the structure and function of Regulatory Affairs. As Director Regulatory Affairs (CMC), you will be part of the teams driving Ascendis' development projects further. You will be a key member of the Regulatory Affairs team and provide effective support to the organization to ensure the best development programs for your designated projects. You will be responsible for strategic and operational regulatory input across CMC with primarily focus on the drug substance part of the product, in collaboration with the rest of the RA team.

Key responsibilities:

- Provide high level strategic and operational regulatory direction and mentorship on projects.
- Provide general regulatory strategies, regulatory requirements for clinical studies and marketing appilaction globally, regulatory strategic development plans and risk assessments, critical issue management and advice on Health Authority interactions.
- Oversee the preparation and submission of CMC/Quality documentation to support investigational and marketing registration packages throughout the world and ensures timelines are met, including writing and review of CMC sections of IND/CTA, NDA/BLA/MAA, and other global submission documents while conforming to local regulatory requirements.
- Liaise and negotiate with global regulatory authorities as needed for CMC aspects pertaining to drug development including resolution of key regulatory CMC issues to expedite approvals.
- Build partnerships with key stakeholders from other functions to ensure that strategic business goals are met through the sharing of knowledge, expertise and the provision of appropriate resources.
- Contribute to internal regulatory policies and procedures to achieve best practices and work processes by writing SOPs
- Support the company through regulatory intelligence efforts in staying abreast of newly issued regulatory laws, guidance and technical publications.

Success criteria

First, ensuring that Ascendis Pharma is compliant with the various regulations and regimes. Second, to get well integrated and become a trusted advisor in the organiztion and teams you are involved in. You manage to deliver on time and with high quality.

Challenges

One challenge is to gain trust and influence amongst all the relevant stakeholders in the development projects. It is extremely important that the candidate is able to draft and communicate solutions in a structured and understandable way and thereby obtain license to operate. It is a challenge to balance your work between the attention to details and the ability to maintain an overview of the entire picture. Ascendis Pharma is a diverse organization in terms of locations – one of the challenges is to knit these locations together and to become a value-adding resource to the entire organization.

Development potential
It is important that the candidate is passionate about creating a sustainable footprint rather than building a career. However, Ascendis Pharma is growing rapidly, as will Regulatory Affairs, and there will be personal development opportunities as the organization grows.

Travelling
10 – 15 days per year.

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

Want to apply?
Please submit your application along with your CV to dk_jobs@ascendispharma.com. Please write 'Director Regulatory Affairs (CMC)' in the subject field. All applications must be submitted in English and are treated confidentially.

For further information, please contact RA Senior Director Eva Gamwell Henriksen on egh@ascendispharma.com.

Ascendis Pharma A/S is an international company with offices in Copenhagen, Germany and the US. Ascendis Pharma is building an integrated biopharmaceutical company to advance its pipeline of long-acting prodrug therapies. They employ their proprietary TransCon technology platform to generate therapeutics with best-in-class profiles that address large markets with significant unmet medical needs. Ascendis Pharma has a diversified and balanced high-value product pipeline, including internal programs and partnerships with market leaders.

Read more at www.ascendispharma.com