Regulatory Affairs CMC Associate Director/Director

Exciting position in a fast-growing biotech company

As Regulatory Affairs CMC Associate Director/Director at Ascendis Pharma you will be part of the teams driving Ascendis' development projects and contribute to setting up the structure and function of Regulatory Affairs. 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 also be responsible for strategic and operational regulatory input across CMC and Device, in collaboration with the rest of the RA team.

With direct report to Senior Director Regulatory Affairs.

Your main tasks are to:

- Provide high level strategic and operational regulatory direction and mentorship on projects
- Provide general regulatory CMC strategies, regulatory requirements for clinical studies and marketing applications globally, CMC input to regulatory strategic development plans and risk assessments, critical issue management and advice on Health Authority interactions.
- Oversee the preparation and submission of CMC 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.

Your qualifications are at least 8-10 years of documented professional experience from a Regulatory Affairs CMC position in the pharmaceutical industry. It would also be preferable if you have experience in synthetic peptides and small molecules. You must have extensive regulatory CMC experience including IND/CTA, NDA/BLA/MAA, lifecycle management, interations with Health Authorities, developing and implementing complex regulatory CMC strategies with a proven track record of significant regulatory accomplishments.

Further, you have the proven ability to drive results and work successfully within a cross-functional team/partnership environment with a high level of professionalism. You must have excellent verbal and written communication skills.

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

You are a person with a proved ability to analyze, define and effectively explain difficult and complex issues to both internal and external stakeholders. You are able to work independently and understand that priorities and drivers constantly change. You have excellent people skills and are skilled in conflict resolution with strong negotiation skills. You have a proven ability to build trust and respect within your organization and you are very committed to delivering outstanding results at all times. You are adaptable with a hands-on attitude and you are able to provide good judgement. Finally, you have the ability to make sound decision that contribute positively to the business.

Travelling: 10 – 15 days/year

Place of work: 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 Partner Jørn Duhn, Unique Human Capital on M +45 21 75 19 25. All applications must be submitted in English and are treated confidentially.

Click here to APPLY.

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