Project Manager
Analytical Development

A broad profile with specialist knowledge

As Manager Regulatory Affairs at Ascendis Pharma you will be a part of the different 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 operational regulatory input across CMC, Non-clinical and Clinical in collaboration with the rest of the RA team.

The regulatory team currently consists of 6 members: 4 members are located in Palo Alto, California including the VP of Regulatory Affairs and 2 members are located in Hellerup, Denmark. The position will report to the Senior Director, Regulatory Affairs, DK.

Your main tasks are:

- Support of INDs and clinical trial applications
- Collaborate in project teams with e.g. scientific advice preparation, orphan drug designation applications, and paediatric investigation plans including writing and supporting regulatory communications
- 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.

You must have a university degree in natural science or a related field, and you have at least five years of documented professional experience from a regulatory affairs position in the pharma industry. If you have experience interacting directly with regulatory authorities on an international scale, that is a plus. This position requires someone who considers his or her background as that of a generalist and who is comfortable in a variety of disciplines including CMC, Clinical, and Non-clinical areas. Dossier preparation experience in the US and the EU is a plus.

You will collaborate with colleagues in Denmark, Germany and US, so excellent people collaboration and communication skills are very important. Furthermore, you must be able to work well independently for the success of your projects, appreciating portfolio priorities. You must be highly committed to delivering outstanding results at all times. You must be an adaptable and robust person with a hands-on attitude. Due to the diversity of our corporate sites in different worldwide time zones, there are times when meetings will be held outside of normal daytime work hours. You should be flexible to accommodate those meeting times.

You are proficient in English at a professional level both written and spoken and you master MS Office. Experience with MS Projects or other project tools are an advantage.

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 our exciting product pipeline.

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.

For more details about the job or the company, please contact Partner, Jørn Duhn 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