

Director, Device Development

Join a Fast Growing Biotech Company

Ascendis Pharma A/S, a visionary and ambitious company, offers you a once-in-a-lifetime opportunity to become a major participant in the further establishment of the structure and function of device development, giving you a unique influence on the way devices are developed in the future.

As Director, Device Development at Ascendis Pharma, you will be responsible for managing the device activities in new drug/device projects with partners and contract manufacturing organizations. Furthermore, you will report directly to the VP, CMC, Pharmaceutical and Device Development.

Your key responsibilities:

- Provide input to and take ownership of design and development of the medical devices used for Ascendis Pharma's combination products
- Coordinate and manage medical device CMOs to assist with medical device development projects
- Ensure that all activities are conducted in compliance with relevant regulatory requirements
- Mature quality system for medical device data generated during medical device development to a commercial readiness setting in order to facilitate transfer to Product Supply
- Ensure that the medical device part for Pharmaceutical Development and the manufacturing process of the projects are conducted optimally with respect to quality, timelines and budget.
- Responsibility for outlining medical device agreements and work orders for specific tasks in cooperation with the legal staff
- Involvement in writing regulatory documentation for the medical device part of INDs/IMPDS.
- Support inter-departmental communication and ensure effective handoffs to execute on important project milestones.
- Report on project progress via monthly status reports.

Ideally, you hold a relevant Master's Degree combined with several years of experience from working with device development and project management.

Qualifications required of the position include having relevant manufacturing and pharmaceutical industry experience in the planning and execution of device development projects, and a proven history of effectively contributing to business plans at both the tactical and strategic levels. Moreover, you have a solid background and experience in working with external partners (CROs, CMOs and consultants) and you have extensive knowledge of medical device regulations as well as other international regulatory guidelines. You are knowledgeable about drug regulations, and you are comfortable managing multiple programs with competing and aggressive time lines. Finally, you can prioritize activities and work independently in a rapidly changing, not fully structured internal and external environment.

You have excellent English communication skills, both spoken and written and you are an advanced user of MS Office, Access and other relevant IT tools or systems.

As a person, you have a high level of drive, ambition, and passion. You take initiative, are persistent, pay a high level of attention to detail and you are goal-oriented. You are comfortable with a risk-

based approach to decision-making in a dynamic environment in which priorities and drivers can change rapidly. You can communicate clearly towards upper management and you are an active project player who cooperates closely with other departments at Ascendis Pharma. Finally, you are quality driven, open-minded, robust, able to stand firm, and you like to have fun.

At Ascendis Pharma you will be part of a stimulating and informal innovative working environment where you will interact with both colleagues and partners to deliver on our ambitious corporate goals.

Travelling: App. 20 – 30 days a year.

Place of work: Ascendis Pharma resides in a wonderful office facility in Tuborg Havn in Hellerup with a view of the harbour, 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 in English and are treated confidentially.

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.

For further information, please see www.ascendispharma.com