Device Director, Commercial Manufacturing

In a Fast Growing Biotech Company

Ascendis Pharma, a visionary and ambitious company, offers you an opportunity to become a major participant in the establishment of the structure and function of a newly established Commercial Manufacturing area. As Device Director at Ascendis Pharma, the main criteria of success will be to establish procedures for monitoring the commercial device manufacturing processes, drive the industrialization phase and post industrialization activities, and to establish close and high-standard collaborations both internal and external with our partners and CMOs. In addition, you will be a value-adding resource, actively contributing within the Product Supply team on challenges related to device processes and manufacturing.

You will report directly to the VP, Commercial Manufacturing.

Your key responsibilities:

- Provide input and take ownership of the industrialization and manufacturing process of the medical devices used for Ascendis Pharma's combination products
- Coordinate and manage medical device CMOs in the commercial manufacturing stage from a technical point of view
- Ensure that all activities are conducted in compliance with relevant regulatory requirements
- Mature quality systems for medical device data and participate and receive tech transfers from development to a commercial readiness in Product Supply
- Ensure that the manufacturing process of the medical devices are conducted optimally with respect to quality, timelines, and budget
- Outline medical device agreements with Global Supply Chain
- Be involved in writing or review regulatory documentation for the medical devices
- Support internal and external communication towards device CMOs and ensure effective handoffs to execute
- Report on progress via monthly status reports and follow up on KPIs
- Establish continuous process monitoring and verification of programs at Ascendis for commercial manufacture at CMOs
- Post Industrialization optimization of manufacturing processes
- Support QA during master batch record updates and release of commercial batches
- Trouble shooting activities at CMOs
- Prepare and make Ascendis and CMOs ready for authority inspections, regarding manufacturing processes and documentation

Ideally, you hold a relevant Master's Degree combined with 7-10 years of experience from working with device development, device tech transfers, and device manufacturing for Combination Products.

Qualifications required of the position include having relevant manufacturing and pharmaceutical industry experience in the planning and execution of device industrialization and manufacturing, 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 (CMOs and consultants) and you have extensive knowledge of medical device regulations and GMP as well as other international regulatory guidelines. Finally, you can prioritize activities and work independently in a rapidly changing 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 to the harbor, the canals, and the sea.

Want to apply? Please forward your application and resume to mail@uhc.dk with the job title and Ascendis Pharma in the subject field.

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