CMC Project Manager
Late Stage Development

In a fast growing biotechnology company

As CMC Project Manager at Ascendis Pharma the main success criteria is to achieve project goals in the CMC project teams and to maintain a close and high-standard cooperation with the CMOs used by Ascendis Pharma. The CMC Project Manager reports to the Senior Director for Late Stage Biologics Development and will be part of a very dedicated and experienced team in a strong science based company.

The main responsibilities are:

- Prepare the drug substance manufacturing process for PPQ, in the company's lead project
- Participate in identifying and driving validation activities, such as process characterization
- Review and approve manufacturing and validation documentation
- Evaluate deviations and change controls from manufacturer
- Outline agreements with CMOs together with the legal staff
- Prepare data and documents for regulatory submission
- Support inter-departmental communication and ensure effective execution on important project milestones.

Ideally, you hold a relevant university degree – preferably a Master of Science in Biology, Chemistry, Engineering, Pharmacy, or the like. A PhD is preferred but not a demand. The successful applicant will already have a proven record of accomplishment in delivering APIs manufactured according to GMP to deadline and on budget. The following qualifications are preferred:

- A minimum of 3 years of experience within the field of CMC in the pharmaceutical industry
- Solid scientific background in downstream processing (e.g. chromatography, filtration technologies)
- Experience with manufacture or up-scaling of manufacturing processes for biologic APIs
- Experience with late stage clinical development projects is an advantage
- Experience with outsourcing of development and GMP manufacturing activities is an advantage
- Experience within regulatory and QA requirements for drug substances
- A natural interest in data and understanding of statistics.

You are proficient in English on a professional level, both written and spoken, and you master MS Office.

You have a personal commitment to delivering results. You are analytical and science-driven and you identify and resolve problems in a timely manner. You are a flexible, adaptable and robust person with a hands-on attitude. You are pragmatic with an open and communicative approach and with the ability to develop effective working relationships with employees at all levels. You are able to handle and deliver on routine jobs when necessary, while at the same time having the ability to move projects forward. You are able to work independently and you have very good interpersonal skills.

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 Ascendis' exciting product pipeline.

Travelling: +/- 40 days/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, Unique Human Capital on M +45 21 75 19 25. All applications must be 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