CMC Professional/ Project Manager CMC – Organic Chemist

Join the Development Team in a leading and fast growing biotech company

Ascendis Pharma is focused on building a leading rare disease company providing meaningful improvements in patients' lives by developing best-in-class therapeutics addressing unmet medical needs by applying Ascendis' TransCon technology platform.

As CMC Professional/ Project Manager CMC – Organic Chemist, you are a science-driven organic chemist with development experience. You will support and optimize the manufacturing processes for the development projects and provide effective support to Ascendis' contract manufacturing organizations (CMOs) for GMP manufacture of starting materials, intermediates, and APIs. The manufacturing processes within the TransCon technology comprise both classic organic chemistry, solid phase peptide synthesis (SPPS) and polymer chemistry, and two peptide projects are facing optimization and up-scaling to support further clinical development.

You will become responsible for the chemical manufacture of building blocks for starting materials, intermediates, and drug substance in one or more of the development projects. Additionally, you will work to ensure continuous good relations and alignment with internal stakeholders and CMOs worldwide and stay updated with insights into their methods and processes. You will join a CMC team of nine highly experienced CMC professionals (three Organic Chemists and six Analytical Chemists), and you will report directly to the Vice President CMC Drug Substance & Analysis.

Criteria of success in the role will be to establish reliable and robust manufacturing procedures at the CMOs to support market clinical supply for the development programs. Moreover, you must contribute actively within the CMC project teams regarding manufacturing challenges, and also establish close

and high-standard collaborations with the CMOs that Ascendis Pharma works closely with and be a value-adding resource to them.

Main areas of responsibility:

- Support Ascendis' CMOs with optimization of the chemical manufacturing processes
- Establish reliable manufacturing processes for GMP manufacture
- In collaboration with the CMOs document the process development, establish master batch records, and other quality related documents and together with the QA organization review executed batch records for batch release
- Coordination of optimization and manufacturing activities between CMOs and Ascendis Pharma as daily point of contact
- Writing of regulatory documentation for the CMC part of INDs/IMPDs and eventually for the registration file

You hold a relevant academic degree – preferably a Master of Science in Chemistry, Engineering, Pharmacy or the like. You have at least 2-5 years of experience within the field of organic chemistry from the pharmaceutical industry. It would be an advantage, if you have experience with up-scaling of manufacturing processes to kg-scale, and with out-sourcing of development and GMP manufacturing activities. Furthermore, your knowledge and experience within the organic chemistry field will enable you to guide project teams at CMOs through conceptual as well as specific practical discussions.

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 is an advantage.

You are a highly motivated individual who enjoys being challenged and working in collaborative environments. Strong interpersonal skills are necessary as you will serve as a major contributor and trusted member of the project development teams. A proven ability to communicate with other development staff in a fast-paced environment is crucial. Finally, an ability to think and manage strategically with attention to detail is a prerequisite, as well as a high energy level, focus, and a passion and sense of urgency for developing important new medicines for devastating diseases.

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: 10-20 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 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.

For further information, please see www.ascendispharma.com