CMC Project Manager – Process Chemistry

Great influence within a newly established process development team

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 their TransCon technology platform.

Ascendis Pharma is looking for a science-driven CMC Project Manager – Process Chemistry with development experience to support and optimize the manufacturing processes for development projects and provide effective support to the 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. This position as CMC Project Manager – Process Chemistry is for a late stage development project with process justification initiated, and process qualification to follow.

You will be part of a highly experienced and dedicated team consisting of 4 chemists, responsible for the chemical development and manufacture of starting materials, intermediates, and drug substance. Additionally, you will work to ensure continuous good relations and alignment with internal stakeholders, CMOs worldwide and stay updated with insights into their methods and processes.

Criteria of success in the role will be to establish reliable and robust manufacturing processes at the CMOs including the documentation for process justification and validation. Transfer of the validated process to Product Supply will be one of the future tasks in this position. Moreover, you must contribute actively within the CMC project teams regarding manufacturing challenges and establish close and high-standard collaborations with the CMOs that Ascendis Pharma works closely with and be a value-adding resource to them.

You report directly to the Director CMC Chemical Development and will be part of a very dedicated and experienced team.

Your main responsibilites are:

- Support the external manufacturing of peptides and peptide conjugates
- Secure a high quality by supporting QA during master batch record updates and release
- Pre-PPQ activities including risk assesment and process justification
- PPQ activities including reviewing and writing of documents to support PPQ
- Review and approve manufacturing and validation documentation
- Writing of regulatory documentation for the CMC drug substance part of INDs/IMPDs, and ultimately for the registration file

You hold a relevant academic degree – preferably a Ph.D. in Chemistry, Engineering, Pharmacy or equivalent.

The successful applicant will have several years of documented practical experience with chemical development and manufacture from the pharmaceutical industry within upscaling of chemical processes. Furthermore, your knowledge and experience within process chemistry will enable you to guide project teams at CMOs mainly placed within Europe through conceptual as well as specific practical discussions. Experience within solid peptide chemistry would be an advantage.

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 CMC project 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 details is a prerequisite, as well as a high energy level, focus, passion and a 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 you will work with highly skilled and experienced colleagues to advance Ascendis' exciting product pipeline.

Travelling: 15 – 25 days per year.

Place of work: Ascendis Pharma resides in a wonderful office facility in Tuborg Havn in Hellerup with a view of the harbor, the canals and the sea.

For more details about the job or the company, please contact Research Consultant Elisabeth Haun, Unique Human Capital on M: +45 28 90 33 88. 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