Process Validation Manager

Great influence on a newly established department

As Process Validation Manager at Ascendis Pharma, the main criteria of success will be, in cooperation with CMC, to establish and ensure reliable and robust chemical manufacturing processes at CMOs that are ready for PPQ and eventually market supply for intermediates and drug substance in one of Ascendis Pharma's development projects. In addition, you will be a value-adding resource, actively contributing within the CMC and PS project teams on challenges related to chemical processes and manufacture**.**

You report directly to the Senior Director Drug Substance Manufacturing and will be part of a very dedicated and experienced team.

Your main responsibilites are:

- External manufacturing of peptide conjugates, including solid phase synthesis
- Pre-PPQ and PPQ activities
- Establishment of continuous process monitoring programs for commercial manufacturing
- Support QA during master batch record updates and release of commercial batches
- Writing of regulatory documentation for marketing approval

You hold a relevant academic degree – preferably a Master of Science in Chemistry, Engineering, Pharmacy or the like**.**

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, risk assessments, PPQ and manufacture under cGMP. 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.

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 challenges and working in a collaborative environment. Strong interpersonal skills are necessary, as you will serve as a major contributor and trusted member of the Product Supply Team. With the task of establishing commercial manufacturing processes, it is a prerequisite that you possess an ability to think and manage strategically with attention to details. You have a high energy level and can focus, distinguish and prioritize among tasks.

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: 20 – 30 days/ 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 submitted 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