



Project Manager Process Validation

Great Influence on a Newly Established Department

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

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

Your main responsibilities are:

- Pre-PPQ activities (Risk assessments, PAR-studies, Challenge studies etc.) and PPQ manufacture of small molecule and polymeric starting materials and intermediates at CMOs
- Support QA during master batch record updates and release of commercial batches
- Establishment of continuous process monitoring programs for commercial manufacturing at CMOs
- 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 and Asia 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, a prerequisite is 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.

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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