Senior Manager Downstream Manufacturing

Work on a late stage project in a fast-growing biotech company

As Senior Manager Downstream Manufacturing at Ascendis Pharma the primary tasks are to ensure a smooth tech-transfer from Development to Commercial Manufacturing and to establish close and high-standard cooperation with the CMOs used by Ascendis Pharma. Additionally, the establishment of process performance tracking tools will be an important part of the work.

For the late stage project, you will be drug substance responsible (downstream) for the commercial manufacturing process and will be participating in outlining pre-launch activities and post PPQ activities at the CMOs that manufacture intermediates and drug substance. You will use your experience within the fields of biologics drug substance manufacturing as well as late-stage development to guide and drive the process for having drug substance manufacturing performed in a timely manner.

The position reports to the Senior Director Drug Substance Manufacturing and the candidate will be a part of a highly dedicated and experienced team.

The main responsibilities are:

- Scientific lead of the biological drug substance manufacturing of intermediates and drug substance
- Responsible for downstream purification activities at the CMOs, including follow up on production metrics and optimization projects
- Involved in authoring regulatory documentation for the NDA/MAA
- Support inter-departmental communication and ensure effective handoffs to execute on important project milestones
- Ensure manufacturing metrics are established and reported
- Identify and lead manufacturing process improvement projects

You hold a relevant university degree – preferably a Masters of Sciences, 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 transferring drug substance manufacturing processes from development to commercial, including pre-launch and post PPQ activities. The following qualifications are appreciated:

- A minimum of 7-8 years of experience within the field of biological drug substance manufacturing and downstream purification from the pharmaceutical industry
- Experience with pre-launch and post PPQ activities such as upscaling/tech transfer of manufacturing processes
- Experience with late stage development and pilot production
- Experience with project management
- Experience with outsourcing of development and GMP drug substance manufacturing activities

- A strong analytical mindset and ability to troubleshoot complex issues
- Experience within regulatory and QA requirements (EMA and FDA regulations) for intermediates/drug substances to be manufactured for market supply
- Experience with cell culture harvest steps is preferred but not a requirement
- Ability to manage details and at the same time ensure a holistic approach towards all steps in the manufacturing process including analyses and regulatory impact

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

You are a person who has 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 can handle and deliver on routine jobs when necessary, while at the same time having the ability to move projects forward.

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 together with highly skilled and experienced colleagues to advance our 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 harbour, the canals and the sea.

For more details about the job or the company, please contact Senior Consultant Belinda Bramsnæs, Unique Human Capital on M +45 28 44 28 44. 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