



## Senior Manager Drug Product

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

**As Senior Manager Drug Product** 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 for commercial aseptic produced Drug Products. Additionally, the establishment of process performance tracking tools and CPVs will be an important part of the job.

For the late stage project, you will be Drug Product Responsible for the commercial manufacturing process and will participate in outlining pre-launch activities and post PPQ activities at CMOs that manufacture drug product(s). You will use your experience within the fields of drug product manufacturing as well as late-stage development to guide and drive the processes to ensure drug product manufacturing in a timely and consistent manner. Moreover, you will be a part of a highly dedicated and experienced team.

#### The main responsibilities are:

- Scientific Lead of the drug product manufacturing of drug product
- Responsible for manufacturing activities at the CMOs, including follow up on production metrics, CPV activities and optimization projects
- Involved in authoring regulatory documentation for the BLA/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
- Manufacturing and technical responsible for drug product CMO(s)

**You hold** a hold a relevant university degree – preferably a Masters of Sciences, Engineering, Pharmacy, or the like.

**The successful applicant** will already have a proven record of accomplishment in transferring drug product manufacturing processes from development to commercial, including pre-launch and post PPQ activities including commercial manufacturing. The following qualifications are appreciated:

- A minimum of 7-8 years of experience within the field of drug product manufacturing from the pharmaceutical industry
- Experience with aseptic processes and freeze drying
- Experience with Combination products
- Experience with pre-launch and post PPQ activities such as upscaling/tech transfer/optimization of manufacturing processes
- Experience with late stage development and pilot production
- Experience with project management
- Experience with outsourcing of GMP drug product manufacturing activities and cooperation with CMOs
- A strong analytical mindset and ability to troubleshoot complex issues



- Experience within regulatory and QA requirements (EMA and FDA regulations) for drug product to be manufactured for market supply
- Ability to manage details while at the same time ensuring 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:** 20 – 30 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 Partner Jørn Duhn, Unique Human Capital on M +45 21 75 19 25 or Research Consultant Elisabeth Haun 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](http://www.ascendispharma.com)