

Senior CMC Professional



A Senior CMC Professional position in a fast growing biotech company

As Senior CMC Professional at Ascendis Pharma, the main success criteria is to create a good understanding of deliverables to the project(s) as part of the CMC Project Team. Additionally, the Senior CMC Professional must establish a close and high-standard cooperation within the CMC Project Team and become a value-adding resource to them.

You report directly to the VP, CMC Pharmaceutical & Device Development and will be part of a very dedicated and experienced team.

Your main responsibilities are:

- For the Phase 3 project TransCon hGH, the Senior CMC Professional will, in cooperation with the Drug Product responsible Director, be responsible for designing, executing, and reporting pharmaceutical development studies supporting the GMP Drug Product
- Ensure statistical tools are used where relevant
- Ensure that tasks are conducted optimally with respect to quality, timeliness, and budget
- Be involved in writing regulatory documentation for the CMC part of an NDA/MAA
- Support inter-departmental communication and ensure effective handoffs to execute on important project milestones
- Report on project progress via line management and project review meetings

Ideally, you hold a Master's Degree in Pharmacy, Engineering or the like.

The successful applicant will have a passion for use of science in the daily work and in delivering reported studies with the right quality. The following qualifications are appreciated:

- 0-5 years of experience within the field of pharmaceutical development from the pharmaceutical industry
- Understanding of regulatory and QA requirements with EMA and FDA regulations for drug products

You are proficient in English 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.

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: 5-10 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