



QA Professional – starting materials, intermediates, and analytical testing

In a Fast Growing Biotech Company

Ascendis Pharma A/S, a visionary and ambitious company, offers you a once-in-a-lifetime opportunity to become a major participant in the further establishment of the structure and function of QA Commercial Operations for starting materials and intermediates.

As QA Professional within QA Commercial Operations, you will be responsible for the quality oversight of starting materials, intermediates, and analytical testing for the first commercial products.

You will work closely with our Contract Manufacturing Organizations (CMOs), manufacturing and development areas internally at Ascendis Pharma, and be a significant part of the Product Release Team in QA. In the position, you will report directly to Senior Director, QA Commercial Operations.

Your key responsibilities:

- Review and verification of batch documentation from CMOs manufacturing starting materials and intermediates
- Review and approval of documentation from analytical testing
- Develop local checklists and procedures for batch review and address potential gaps for local processes and procedures
- Follow-up on deviations and CAPA's related to starting materials and intermediates
- Quality assessment of changes to manufacturing processes, materials, and procedures and ensure applicable and appropriate documentation
- Review and approve process validation documents
- Establish regular communication with key personnel at CMOs, incl. face-to-face meetings and Business Reviews
- Collect and analyze data supporting GMP performance, quality KPI's, and goals
- Compile CMO evaluations and author – with CMOs – sections of Annual Product Reviews
- Participate, as Subject Matter Expert (SME) in compliance audits of CMOs
- Keep abreast with changes in relevant product guidelines and regulatory requirements and ensure cGMP at Ascendis and CMOs

You hold a relevant Master's Degree combined with a minimum of 5 years of experience from working with medicinal products in a QA, QC, or manufacturing role.

The position as QA professional at Ascendis Pharma requires thorough knowledge of US and EU GMP regulations and requirements, and experience in working with quality aspects of starting materials, intermediates, and analytical testing. If you have experience from working with CMOs, it will be an advantage.

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

As a person, you are meticulous with a high level of attention to details. You are clear and persistent in your expectations and requirements to quality, while at the same time being pragmatic and flexible in your approach. You communicate clearly, both internally and externally towards CMOs and other stakeholders.

At Ascendis Pharma, you will be part of a stimulating, informal, and innovative working environment, where you will interact with both colleagues and partners to deliver on Ascendis' ambitious corporate goals. You will be part of an expanding QA-organization overseeing development, clinical, and commercial activities

Travelling: 10-15 days/year.

Place of work: Ascendis Pharma resides in a wonderful office facility in Tuborg Havn in Hellerup with a view of the harbour, the canals and the sea.

For more details about the job or the company, please contact Senior Consultant, Jannie Jensen, Unique Human Capital on M +45 29 72 78 86. All applications must be submitted in English and are treated confidentially.

Want to apply? Please forward your application and resume to mail@uhc.dk with the job title and Ascendis Pharma in the subject field.

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