QA Professional – Drug Substance and Analytical Testing

Join 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 in a growing organization with ambitious goals.

As QA Professional – Drug Substance and Analytical Testing, you will be responsible for the quality oversight of the manufacturing and testing of Drug Substance for the first commercial products. You will work closely with Ascendis' Contract Manufacturing Organizations (CMOs), internal manufacturing and development areas, and be a significant part of the Product Release Team in QA. You will report directly to Senior Director, QA Commercial Operations.

Your key responsibilities:

- Review and verification of batch documentation from CMO manufacturing Drug Substance
- Review and approval of documentation from analytical testing
- Follow-up on deviations, and CAPA's related to Drug Substance
- 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 KPIs, and goals
- Compile CMO evaluations and author – with CMOs – sections of Annual Product Reviews
- Be part of the QA team for developing local procedures for batch review and address potential gaps for local processes and procedures
- 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 QA/QC or Manufacturing.

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 fermentation, purification and analytical testing of Drug Substance intermediate and Drug Substance.
If you have experience from working with CMOs, it would be an advantage.

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

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 harbor, the canals and the sea.

For more details about the job or the company, please contact Senior Consultant, Louise Nielsen at M +45 29 74 24 24. All applications must be submitted in English and are treated confidentially.

Click here to APPLY.

Ascendis Pharma *is an entrepreneurial and fast-growing company where skilled, agile and highly resourceful professionals can truly make their mark. Ascendis offers a dynamic place for employees to grow and develop their skills, while influencing the direction of this global company.*