QC Manager Drug Substance for Product Supply

Join the Product Supply Team in a leading and fast-growing biotech company

Ascendis Pharma is currently looking to expand its resources to support product supply in the activities of its TransCon Growth Hormone program. The manufacturing processes in the TransCon Growth Hormone program are in the PPQ stage and approaching the commercial phase. Therefore, Ascendis Pharma is looking to hire a QC Manager within analytical chemistry to provide effective analytical support to large molecule drug substance, starting materials and intermediates.

You will become one point of contact in analytical matters between Ascendis and specified Contract Manufacturing Organizations (CMOs). You will work to ensure continuous good relations and alignment with CMOs worldwide and stay updated with insights into their methods and processes. It is expected that in the collaboration you will contribute in areas such as analytical testing and test methods as well as regulatory guidelines and requirements on analytical validation. You will join a team of highly experienced colleagues and you will report to the Director, Quality Control (QC).

Criteria of success in the role will be to coordinate analytical activities for the commercial manufacturing of large molecule drug substance, starting materials and intermediates for TransCon Growth Hormone. Moreover, you are expected to actively contribute to the establishment of continuous process verification programs to the annual product review process and establish close and high-standard collaborations with the CMOs.

Your main responsibilites are:

- Coordination of analytical activities between Ascendis and CMOs
- Scientific and GMP-compliance review of analytical deviations and changes
- Review and approval of analytical validation activities performed by the CMOs
- Review of analytical validation, release and stability testing incl. trending and control charts.
- Facilitate and support analytical performance and efficiency improvements
- Establish procedures for internal review and handling of analytical data for commercial manufacturing
- Write regulatory documentation and follow-up on post-approval commitments to authorities
- Keep abreast with scientific and regulatory development in areas of analytical testing, analytical methods and analytical validation.

You hold a relevant academic degree – preferably a Master of Science in Chemistry, Engineering, Pharmacy or the like. You have several years of documented practical analytical experience from the pharmaceutical industry within chromatographic analyses (HPLC/UPLC, LC-MS, SE-HPLC), either from an Analytical Development Laboratory or from a QC Laboratory. It will be an advantage if you have experience with cell-based potency assays and ELISA. Furthermore, your knowledge and experience within the analytical chemistry field will enable you to guide project teams at CMOs through conceptual as well as specific practical discussions. Preferably, you have analytical experience with analysis of large molecules, and preferably with polymers, proteins and/or peptides as well.

You are proficient in English at a professional level, both written and spoken, and you master MS Office. Experience with MS Projects or other project tools is an advantage.

You have a structured and systematic approach to solving tasks. As the job involves many stakeholders and coordination of activities both internally and externally, you thrive with being in contact with new people. You are a highly motivated individual who enjoys being challenged and working in collaborative environments. You possess a high energy level and focus on details. You have excellent abilities in terms of keeping an overview even with many active tasks at the same time.

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 preparing Ascendis Pharma to become a pharmaceutical company with commercial production and will work with highly skilled and experienced colleagues.

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 harbor, the canals, and the sea.

For more details about the job or the company, please contact Senior Consultant Louise Nielsen, Unique Human Capital on M: +45 29 74 24 24. 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