QC Chemist for Product Supply

Facilitate and support analytical activities 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 Chemist within analytical chemistry to provide effective analytical support to small molecule and polymeric starting materials and intermediates.

You will, as an Analytical/QC Expert, 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. In the collaboration, it is expected that 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 directly to the Senior Director, Chemical Manufacturing.

Criteria of success in the role will be to coordinate analytical activities for the commercial manufacturing of 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
- Writing of regulatory documentation and follow-up on post-approval commitments to autorities
- 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. Furthermore, your knowledge and experience within the analytical chemistry field will enable you to guide project teams at CMOs mainly placed within Europe through conceptual as well as specific practical discussions. Preferably, you have analytical experience with analysis of small molecules, polymers, proteins, and/or peptides.

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 are a highly motivated individual who enjoys being challenged and working in collaborative environments. Strong interpersonal skills are necessary as you will serve as a major contributor and trusted member of the project development teams. A proven ability to communicate with many different stakeholders internally as well as externally is crucial. Finally, an ability to think and manage strategically with attention to detail is a prerequisite, as well as having a high energy level, focus, and a passion and sense of urgency for developing important new medicines for devastating diseases.

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 with highly skilled and experienced colleagues to advance the exciting product pipeline.

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 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.

For further information, please see www.ascendispharma.com