Project Manager Analytical Development

Join the Development team in a leading and fast-growing biotech company

Ascendis Pharma is expanding its CMC resources to support and mature their peptide development projects and are now looking to hire a passionate Project Manager within analytical development to provide effective analytical support to Ascendis' Phase 2 and Phase 3 projects.

As Project Manager Analytical Development at Ascendis Pharma you will be responsible for supporting and outsourcing analytical method development activities at Contract Manufacturing Organizations (CMOs), including method validation, release and stability testing activities for starting materials, intermediates, peptide APIs and DPs. As Project Manager within the CMC Drug Substance & Analysis group, you will work to ensure continuous good relations and alignment with Ascendis' CMOs worldwide and stay updated with insights into their analytical methods and manufacturing processes. You will get a job with large day-to-day variation in tasks: one day you will be looking at analytical raw data, another day trouble shooting on instrument variation, and yet a third day planning analytical and CMC activities with your colleagues both internally and at Ascendis' CMOs/CROs. You will join a team of 10 highly experienced CMC professionals (3 Organic Chemists and 7 Analytical Chemists).

With direct report to the Vice President CMC Drug Substance & Analysis.

Your main tasks are:

- Project management/coordination of analytical activities between CMOs/CROs and Ascendis Pharma as daily point of contact
- Support the analytical team at CMOs/CROs and at the Ascendis Pharma Heidelberg facility with analytical troubleshooting
- Discuss and monitor execution of the analytical validation strategies
- Monitor and review stability data. Perform trending of data
- Support identification of impurities
- Write regulatory documentation for the CMC part of INDs/IMPDs, and eventually for the registration file
- Outline agreements and work orders for analytical tasks within Ascendis Pharma's development projects with Ascendis Pharma's legal staff.

Success criteria in this role will be to establish reliable and robust analytical methods for Ascendis' peptide projects and to support analytical development activities at the CMOs/CROs. You will contribute actively within the CMC project teams regarding analytical challenges and establish close and high-standard collaborations with the CMOs/CROs that Ascendis Pharma works with.

Your qualifications are at least 5 – 7 years of documented practical analytical experience from the pharmaceutical industry within peptide chromatographic analyses (HPLC/UHPLC, LC-MS, SEC), either from an Analytical Development Laboratory or from a QC Laboratory. It would be an advantage if you have experience with working with oversight of external collaborators such as CMOs/CROs, as well as have insight into the CMC development process. Furthermore, you have a large interest in being involved in complex analytical chemistry. 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 Master's Degree preferably a Master of Science in Chemistry, Engineering, Pharmacy or similar.

You are a person who thrives in an environment with focus on collaboration and communication. You are highly motivated, self-reliant and you enjoy being professionally challenged. 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 other development staff and external collaborators in a fast-paced environment is crucial. You pay attention to the detail but not on behalf of the overall picture and you have a high energy level. Finally, you must have 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 Ascendis' exciting pipeline.

Travelling: 10 – 20 days per year

Domicile: 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 Partner Jørn Duhn, Unique Human Capital on M +45 21 75 19 25. All applications must be 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