Sr. Manager Clinical Quality Assurance

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 study of ground-breaking therapies in the clinical setting.

As Sr. Manager within Clinical Quality Assurance, you will be responsible for the GCP compliance oversight for the clinical development for new and novel therapies.

You will work closely with Ascendis' Clinical Operations team, Contract Research Organizations and Clinical Sites in assessing the clinical compliance for studies occurring around the world. You will also be a significant part of the Global Quality Assurance team, providing experience and insight to Ascendis Pharma's ongoing QA needs. In the position, you will report directly to Senior Director, Clinical QA who is based in the United States.

Your key responsibilities:

- Be the Audit Lead in a variety of audits e.g. CRO, Clinical Service Vendors and Clinical Sites
- Follow-up on deviations, and CAPAs related to clinical studies
- Write, review and approve audit reports
- Establish regular communication with key personnel at CROs, clinical service vendors and within the Clinical and Regulatory team
- Write, review and approve SOPs in support of GCP needs
- Keep abreast with changes in relevant guidelines and regulatory requirements and ensure GCP requirements are met at Ascendis and across the studies

You hold a relevant Bachelor's degree combined with a minimum of 10 years of experience gained from working with clinical trials as either CRA, Clinical Trial Manager or QA Auditor.

The position as Sr. Manager at Ascendis Pharma requires thorough knowledge of US, EU and global GCP regulations and requirements. Candidates with experience with Combination Products or Biologics will have 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 and pay 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 CROs, Clinical Sites 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: 7-10 days/month.

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 Partner Jørn Duhn, Unique Human Capital on M: +45 21 75 19 25 or 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 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