QA Manager GMP

In a fast growing Biotech Company

Ascendis Pharma is focused on creating drug candidates that are improved versions of existing drugs, yielding more effective, lower risk drugs with a new patent life. Ascendis Pharma is in the process of expanding its pipeline with more drug candidates, and at the same time, Ascendis Pharma is putting much emphasis on the further clinical development of its TransCon Growth Hormone programme. Ascendis Pharma is therefore looking for a QA Manager GMP to be responsible for ensuring the quality work of their CMO and CRO partners.

The QA Manager GMP will work closely with the Senior Director of Development QA to support ongoing responsibilities and defined goals by ensuring that activities are in compliance with Ascendis Pharma's Quality Management System. The QA Manager GMP will be responsible for leading initiatives to ensure process consistency at all Ascendis Pharma sites and for ensuring a smooth quality transition for the CMO and CRO partners to Ascendis Pharma.

Your main tasks are:

- CMO responsibility regarding Compliance & Quality.
- Apply global regulations, agency guidelines, and internal procedures to ensure compliance.
- Schedule, plan and prepare CMO, CRO and/or laboratory for audits. May also audit internal processes, submission documents etc. in accordance with the audit plan or as requested.
- Conduct audits, and prepare and submit audit reports for review and input.

- Communicate audit results to stakeholders.
- Assist with GMP inspection readiness activities for regulatory authority inspections and coordinate tracking of document requests, responses, and supporting documentation during inspections.
- Develop and implement GxP systems and procedures including SOPs, policies, forms, and tools such as excel spreadsheets or reports.
- Identify and communicate quality or compliance risks and participate in the development of an appropriate plan to address risks.
- Ensure that documentation, procedures and processes supporting development programs are maintained in compliance with company and industry standards and global regulations.
- Maintain working knowledge of current FDA, EU, and other global regulation and guidance governing Good Manufacturing Practice (GMP), Pharmacovigilance (PV) and Good Laboratory Practice (GLP) activities.

You hold a Master of Science degree (MSc) or equivalent. A minimum of 3-5 years of experience in a medium to large scale matrix organization is required, which includes an applicable compliance related field and/or equivalent experience in a related R&D area. A track record in operational deliverables, thorough project planning, and managing supportive capabilities is required.

The position as QA Manager GMP at Ascendis Pharma requires a thorough knowledge of the drug development process, good knowledge of worldwide GxP compliance regulations, sound research and development practices, scientific and quality terminology, industry quality assurance and management procedures and policies, and quality evaluation techniques.

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

You are a person who has a personal commitment to delivering results. You are analytical and science-driven and you identify and resolve problems in a timely manner. You are a flexible, adaptable, and robust person with a hands-on attitude. You are pragmatic with an open and communicative approach, and have the ability to develop effective working relationships with employees at all levels. You are able to handle and deliver on routine jobs when necessary, while at the same time, you have the ability to move projects forward.

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

Travelling: 20 days/year.

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 Senior Consultant, Jannie Jensen, Unique Human Capital on M: +45 29 72 78 86. All applications must be submitted in English and are treated confidentially.

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