QA Manager – Medical Devices and Combination Products

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 Medical Device and Combination Product Development to establish commercial processes in medical device and combination product manufacturing, assembly and packaging.

As QA Manager within Medical Devices and Combination Products, you will hold the key competence within quality oversight of medical devices and combination products. You will be involved in transfer activities from development to commercial manufacturing and validation activities for commercial manufacturing and routine manufacturing activities. These activities also include assembly and packaging operation as well as development of printed packaging materials for clinical and commercial use.

You will be responsible for the quality assurance of medical device and combination product activities supporting commercial manufacturing. You will work closely with development and commercial areas internally in Ascendis Pharma and externally with contract manufacturing organizations (CMOs).

Your key responsibilities:

- Provide Quality Assurance input to the transfer from development to commercial manufacturing of medical device and combination products, and ensure that all activities are conducted in compliance with Ascendis' QMS and relevant regulatory requirements
- Review and approve medical device and combination product documentation, validation and manufacturing documents
- QA oversight of manufacturing and packaging activities for clinical and commercial use
- QA review and approval of printed packaging materials from CMOs
- QA review and approval of assembly and packaging validation documents from CMOs
- Batch record review and approval for assembly and packaging activities
- Review of documentation from medical device and packaging suppliers to ensure that all activities comply with quality requirements and Ascendis' procedures
- Follow-up with CMOs on medical device, assembly and packaging deviations and non-conformities
- Prepare quality assessment of changes to manufacturing processes, materials, design and procedures and ensure applicable and appropriate documentation
- Identify and establish necessary Ascendis procedures for quality assurance of medical devices, combination products, assembly and packaging processes
- Participate, as Medical Device, Combination Product, Assembly and Packaging Quality Specialist in compliance audits of CMOs
- Keep abreast with changes in relevant medical device and combination product standards, guidances and regulatory requirements and ensure cGMP at Ascendis and CMOs

You hold a relevant Master's degree combined with a minimum of 10 years of experience from working with medical device or combination product development, manufacturing or quality assurance. You have extensive knowledge of international, US and EU medical device and combination product regulations and standards, such as 21 CFR part 820, MDD/MDR and ISO 13485, and experience from working with quality aspects of medical device development or manufacturing, combination products and GMP in general. As

you will have frequent, direct communication with CMOs, you must have excellent English communication skills, both spoken and written.

As a person, you are meticulous with 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 are self-motivated and able to work independently. You can communicate clearly, both internally and externally towards CMOs 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.

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 in English and are treated confidentially.

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.

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