QA Manager, Medical Device

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 further establishment of the structure and function of device development, giving you a unique influence on the way devices will be developed in the future.

As QA Manager, Medical Device, you will hold the key competence within quality oversight of medical devices and combination products.

You will be responsible for the quality assurance of all device activities in development of new device projects and the commercial manufacturing of devices. You will work closely with development and commercial areas internally in Ascendis Pharma and with contract manufacturing organisations (CMOs).

Your key responsibilities:

- Provide Quality Assurance input to the development and clinical/commercial manufacturing of medical devices and combination products, and ensure that all activities are conducted in compliance with Ascendis' and other relevant regulatory requirements
- QA oversight of commercial packaging activities
- Batch record review and review of other documentation from medical device and packaging suppliers, and ensure that all activities comply with quality requirements and Ascendis' procedures
- Follow-up with CMOs on medical device and packaging deviations and non-conformities

- Quality assessment of changes to manufacturing processes, materials, design and procedures and ensure applicable and appropriate documentation
- Review and approve medical device and combination product validation documents, incl. Design History Files.
- Review and approve packaging validation documents
- Identify and establish necessary Ascendis procedures for quality assurance of medical devices, combination products and related areas
- Participate, as Medical Device/Combination Product and Packaging Specialist, in compliance audits of CMOs
- Keep abreast with changes in relevant medical device and combination product guidelines and regulatory requirements and ensure cGMP at Ascendis and CMOs

You hold a relevant Master's Degree combined with a minimum of 5 years of experience from working with medical device manufacturing or medical device quality assurance. Furthermore, it is an advantage if you have knowledge within combination products. You have extensive knowledge of International, US and EU medical device and combination product regulations and requirements, such as 21 CFR part 820, MDD 1993/42/EEC and ISO 13485, and experience in working with quality aspects of medical device 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. However, at the same time being pragmatic and flexible in your approach. 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 our 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 Jannie Jensen, Unique Human Capital on M +45 29 72 78 86. 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.

Apply: Click here

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