OPERATIONS/PROCESS QUALITY MANAGER

Posted on 7 juli, 2021

Company Name Oticon Medical AB

Location Göteborg

Job Description

Do you want to improve the life of people with a hearing disability? Do you have a passion for Production and Process Development within medical devices? Then we have an exciting opportunity for you as our new Operations/Process Quality Manager at Oticon Medical BAHS in Gothenburg.

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. We are now looking for a great new member to our Operations team where we, among other key tasks, are responsible for purchasing, production and logistics in collaboration with external partners.

As Operations/Process Quality Manager, reporting to Head of Operations, you will be responsible for production and process developmen of all our outsourced production and distribution processes. You will be involved in setting up and maintaining production processes in collaboration with our suppliers as part of product development projects, supplier change projects and projects related to distribution and return flows. You ensure production quality of all our medical devices by securing that activities are well defined, planned, documented, and executed according to Medical Device standards and regulations, all in close collaboration with internal and external partners.

Your responsibilities

- Secure production and process quality for all Oticon Medical BAHS products through outsourced partners.
- Create input to production and process requirement specifications including traceability and handling procedures.
- Develop and maintain specifications, instructions and procedures for production quality monitoring and release of products.
- Develop process validation master plans, ensure establishment, and maintain process quality documentation.
- Process owner of the sterilization process – E-beam & ETO
- Drive CAPAs and follow up of corrective actions related to production and process performance.

- Represent production and process control as subject matter expert during external audits.
- Drive the supplier audit plan, execute audits as lead auditor, document, and follow-up.
- Prepare yearly supplier evaluation reports including performance KPI´s.
- Provide process performance data to management QMS review

Your experience and qualifications

You have a minimum of 5 years of professional experience, preferably related to production quality of high-class medical devices. You have thorough knowledge of MDSAP, ISO 13485 and GMP requirements. Experience from sterilization processes validation both E-beam & ETO is highly meriting.

You are stimulated by building relationships and implementing improvements and new processes as well as working in cross functional teams with your colleagues.

Your professional style is characterized by your ability to work structured and focused in a technical and professional manner.

Besides that, we expect that you are pragmatic and strive for efficiency in all that you do.

- You think and act holistically and like to take responsibility
- You are skilled in creating and maintaining good relations to all parts of the organization
- You know how to benefit from multi-site and multi-cultural development teams

Besides the above mentioned, we prefer flexible candidates who can travel up to 20 days per year.

We dare to make a difference

Together with skilled colleagues, you are part of a dynamic environment based on trust and openness. We are an extremely successful company – the fastest growing company in the fastest-growing segment of hearing healthcare. We are proud of being scientific- and business-driven at the same time, with the expectation of constantly producing best-in-class products. You will be working in a bright and open workplace, where a flexible working environment, knowledge sharing, and professional respect makes it both challenging and meaningful to go to work.

Would you like to know more?

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter in English or Swedish to tom.bergqvist@moveup.se

If you have questions regarding Oticon or this open position, please contact Tom at +46 (0)733 87 27 22.

We look forward to your application!

By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that we have the right to share this information with third parties (our client). You can revoke the consent whenever you want.

Om företag

Oticon Medical *is part of Demant group with more than 14.500 employees across the world. Oticon Medical is the fastest growing manufacturer of bone anchored and cochlear implant hearing systems for children and adults. At Oticon Medical we combine more than a century of experience in audiology and sound processing from Oticon with decades of pioneering experience in hearing implant technology. Our connection to Oticon gives us unique access to knowledge, resources and technology that we use for developing innovative and life-changing implantable hearing systems.*

Consultant Name Tom Bergqvist

Consultant Number 0733872722

Consultant Email tom.bergqvist@moveup.se

Cosultant Linkdin https://www.linkedin.com/in/tombergqvist/