Join us in improving the quality of life for people suffering from neurological diseases!

At Combinostics – we are driven by making a significant difference in the early detection and management of neurological disorders.

We believe that better use of AI-powered diagnostics and follow-ups for clinicians around the world is worth developing even further - ultimately providing people with better quality of life. We do this through our market leading Radiology & Neurology product suites. We already provide best-in-class early detection support and disease management of neurological diseases, such as Alzheimer's Disease and Multiple Sclerosis (MS). Meanwhile, we continually develop the software products to provide solutions for a wider spectrum of neurological diseases.

At Combinostics, we let industry specialists, creative developers and commercial teams come together and unleash their creativity. Together we are building one of the most exciting software solutions for deployment in medical practices today. Having a proven product in the market already, the next step in our journey is to scale up our commercial activities.

We have an integrated Quality- and Information Security Management System, certified to both ISO 13485 and ISO 27001. Our commercial products are medical devices, CE-marked under MDR and FDA 510(k) cleared. We are in the process of submitting additional products for regulatory approvals. In the future, we may also expand to other markets.

ABOUT THE ROLE

We are now looking for a full-time employee as **Head of QA**. This is a critical role, managing our quality management system (QMS) and our information security management system (ISMS) as well as managing regulatory aspects of our launched products and supporting the launch of new products. The QA-function is today managed through a consultancy company.

The Head of QA is responsible for our regulatory compliance (PRRC). This role includes staying in touch with regulatory bodies, managing internal and external audits, reviewing and approving product documentation etc. The quality work is conducted in close collaboration with the R&D team located in Tampere, Finland. Because of this, we believe that the successful candidate resides in Finland, ideally in Tampere but other locations in Finland allowing for frequent travel to Tampere is also possible.

ABOUT YOU

We put great emphasis on your personal characteristics. You are proactive and flexible with a hands-on-mentality while also having a natural ability to collaborate across the entire Team. You have a minimum of 5 years' experience in quality assurance in the medical device field including experience in medical device software. This means that you have documented experience in ISO13485 and IEC 62304, and ideally also in ISO27001 and that you have participated in medical device product launches and are familiar with working with Competent Authorities and Notified Bodies.

You are motivated to perform with a sense of urgency in your role, contributing to your own result as well as the Team's. You have a high attention to detail and have a structured approach in everything you do. You are flexible and sensitive to the views of others and find it fun when new ways of thinking take you to new solutions.

RESPONSIBILITIES

- Overall responsibility for ensuring that our QMS and ISMS are effectively maintained.
- Promotion of awareness of quality management system requirements throughout the organization.
- Having the role as Person Responsible for Regulatory Compliance (PRRC) according to the MDR.
- Having the role as Management Representative.
- Ensure regulatory approval and company's compliance with quality and certification requirements.
- Communicate with regulatory bodies and competent authorities in compliance issues including certification/registration processes and vigilance.
- Schedule and participate in internal and external audits.
- Review product documentation, including marketing material, to ensure regulatory compliance.

WHAT'S NEEDED

- MSc or equivalent in electrical engineering, computer science or similar.
- Minimum 5 years of experience in QA-role in medical device industry.
- Certified training in ISO13485 and ISO27001.
- Experience with medical device software development and maintenance.
- Great communication skills with colleagues and regulatory bodies.
- Fluent in English.

Desired:

- Experience with medical imaging software.
- Experience from having worked with cloud-based software.

WHAT WE OFFER

- A unique opportunity to significantly contribute to the success of Combinostics.
- Joining early in a multicultural company with ambitious global growth plans.
- Competitive salary.
- An opportunity to become shareholder in Combinostics.

WHO WE ARE

The key to Combinostics' success is with our talented employees. Providing our employees with the best possible conditions for feeling good, having fun, being able to succeed and develop at work is an internal mission that drives Combinostics. Although we believe that technology is important for success in our work, we see that people are even more important. We believe that diversity and differences make us stronger as a Team and result in better solutions for our customers. Combinostics has offices in both Europe and the US, and we operate in a hybrid work environment.