Surfix BV
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Job Profile

Quality Assurance and Regulatory Affairs (QARA) Officer

Who we are

Surfix B.V. headquartered in the Netherlands, is at the forefront of medical technology innovation. The company's pioneering photonic diagnostics platform integrates six cutting-edge technologies, creating a multimodal point-of-care solution with lab-level precision.

This versatile instrument allows for the execution of both immuno- and molecular assays, and e.g., running liquid biopsy-based samples with ultra-low concentrations of biomarkers. Surfix is committed to collaborating with strategic partners on the co-development of assays for point-of-care applications, including cancer, infectious diseases, and cardiac disease.

At the core of Surfix's platform is a photonic biosensor, which comprises a biochip and a microfluidic cartridge, both enhanced with Surfix's proprietary nanocoatings. This combination of technologies ensures the platform's high sensitivity, reliability, and rapid results. Additionally, a compact desktop reader, specifically designed for this platform, is in development to enhance its ease of use and suitability for point-of-care applications.

On our website (www.surfixdiagnostics.com) you can read more.

What we are looking for

We are seeking a talented QARA manager to maintain and where needed improve the quality level of our organization and prepare for the regulatory requirements related to the future IVDR and FDA approvals of our instrument and cartridges.

In this role you are responsible for the maintenance of a robust Quality Management System (QMS) consistent with ISO 13485. You will work closely with other departments providing QA support and guidance to operational activities, ensuring that all customer and regulatory requirements are met. You will be responsible for correspondence with regulatory bodies pertaining to regulations and approval for the IVD medical device

At Surfix Diagnostics, you will join a highly educated, multidisciplinary, and international team dedicated to developing and marketing a fast, reliable, and innovative photonic diagnostics platform for various diagnostic tests in the global oncology and other liquid biopsy-based markets.

The ideal candidate has experience in a startup environment and thrives on the journey towards the scale-up phase.

Are you a highly motivated team player and have sound judgment, effective communication and problem-solving skills? Would you like to be part of a young company bringing revolutionary and lifesaving products to the market? Then this job might be a perfect opportunity, and we are looking forward to meeting you.

What you will do

- Manage quality tasks including change control, batch release and process validation
- Participate in quality related investigations to resolve production, audit, and customer issues
- Create, approve, and maintain the Standard Operating Procedures (SOP) and ongoing management of the Document Control System
- Organize and facilitate product and process risk assessments
- Provide training and support to other departments on procedures and core processes
- Report and follow up on quality key performance indicators in a timely manner
- Maintain the electronic document management system
- Execute internal and supplier audits and support external audits
- Ensure all applicable standards are met in relation to regulatory and customer requirements
- Identify and support quality process improvements
- Ensure registration and approval of medical device with regulatory agencies

What you bring

- Bachelor's or master's degree in science, Biology or Chemistry or equivalent combination of education and experience
- At least 3 years of experience as a Quality Assurance Officer in a product development manufacturing environment, preferably in the in-vitro diagnostics industry
- Excellent language skills in English is a requirement
- Knowledge and practical application of Quality Management System ISO 13485 and In-Vitro Diagnostics Regulation (EU) 2017/746 is a must
- Advanced critical thinking and organizing skills
- Self-starter and ability to work independently
- Excellent communication and relationship management skills
- Team player with a hands-on mentality
- Preferably living in (a radius of 50 km around) Wageningen/Ede

What we offer you

- Join a great team of enthusiastic, international, and highly educated professionals in a startup environment
- An efficient organization with a focus on innovation and clear lines of communication
- Diverse range of activities with ample room for initiative
- Opportunity for professional growth alongside the company
- Competitive working conditions and benefits
- Direct reporting to the COO

Your future location

Hybrid: At the Surfix facilities in Wageningen (Agro Business Park 2) and at your home office

Type

Part-Time (0.8 FTE)

Interested

We'd like to hear from you. Please send your CV with a cover letter outlining your motivation and interest to Arthur Blom, COO, at career@surfixdx.com. For more information, you can contact him at +31 85 488 1285.

Apply now and be a part of our exciting journey!