

We are Mobidiag, team of roughly 130 people in 4 countries driven by creating something meaningful and helping the world to be a better place. We develop and provide industry-leading solutions for in vitro diagnostics of infectious diseases and help prevent the spreading of antibiotic resistances by making molecular diagnostics fast, accurate and accessible. By using our tests patients get targeted treatment faster, more efficiently and more reliably.

We are now looking a

SENIOR QUALITY ENGINEER, RISK MANAGEMENT & CHANGE CONTROL

to join our growing Quality & Regulatory team in Espoo. In this position you will be responsible for leading and coordinating Risk and Change Management activities and ensuring they are conducted according to regulatory requirements. You will provide subject matter expertise regarding Risk Management and Change Control as well as technical leadership on activities related to both processes.

Your key responsibilities are the following:

- Lead and coordinate Risk Management activities during the whole IVD medical device life cycle
- Responsible for Risk Management file compilation and maintenance
- Monitor and ensure continuing acceptability of the benefit-risk ratio during the whole life cycle
- Lead Change Management to IVD medical devices and their validated manufacturing processes
- Ensure Risk Management and Change Management activities meet regulatory requirements in the target market area
- Provide Risk Management and Change Management technical expertise and training within the organization

Ideally, you should have:

- Master's degree in Biosciences, Medicine, Pharmacology, Engineering or corresponding coupled with minimum of 5 years of work experience in quality management in an applicable field, preferably IVD
- Experience in Risk and Change management (e.g. according to ISO 13485, ISO 14971 and IEC 62304)
- Good understanding of regulatory IVD requirements in Europe (Directive 98/79/EC and Regulation (EU) 2017/746)
- Good written and verbal communication skills in English; Finnish and French skills are seen as a great asset
- Excellent interpersonal and influencing skills; able to express ideas and collaborate effectively with multidisciplinary teams at all levels

We offer you:

- Possibility to grow and expand your expertise – working in a growing company you will get involved in full spectrum of challenges
- Having fun – your future team members are enthusiastic, energetic and talented
- Opportunities to learn continuously – we believe in investing in our employees and ensuring their knowhow is top notch

- Balance between work and leisure time – we appreciate you when you're not working too, and want to ensure you can recharge and have fulfilled leisure time

If you have any questions, please contact Director, Quality & Regulatory Timo Soininen by phone at +358 40 535 6520 either on February 17th at 9 – 10 am and on February 19th at 11 am – 12 am. If you already made your decision, please send your CV and application to HR Manager Hanna Osara at hanna.osara@mobidiag.com by February 23rd. Use "Senior Quality Engineer" in the subject line.