Mobidiag develops innovative molecular solutions to advance the diagnosis of infectious diseases and antibiotic resistances. With its broad range of tests and instruments based on well-established PCR technology, Mobidiag allows fast and cost-efficient detection of most common bacteria, parasites, viruses and antibiotic resistances to answer any microbiology laboratory requirements. Mobidiag is headquartered in Espoo, Finland with subsidiaries in France, Sweden and UK. For more information about Mobidiag, please visit www.mobidiag.com

We are looking for a

SENIOR QUALITY ENGINEER

to join our Quality & Regulatory team in Espoo

Senior Quality Engineer is responsible for development, implementation and maintenance of Quality Management System. He/she leads company CAPA procedure to ensure and improve compliance with regulatory and QMS requirements. In addition, Senior Quality Engineer partners with R&D, production and sales & marketing with the overall focus of developing and reviewing operational processes and practices.

Key responsibilities:

Develop, maintain and manage Mobidiag's Quality Management System by

- developing and reviewing associated documents
- developing and reviewing operational processes and work practices
- monitoring performance level and effectiveness of the company QMS
- gathering and assessing QMS and product associated data
- planning and implementation of improvement actions
- participating in product risk management
- providing quality and regulatory expertise and enabling collaborative relationships with R&D, production and sales & marketing

We expect you to have some of the following qualifications and interest to grow on the others:

- Master's degree or comparable education in a relevant field with minimum of 5 years relevant work experience.
- Strong knowledge and understanding of CAPA procedure
- Experience in software validation (preferably in compliance with 21 CFR Part 11)
- Working knowledge and experience in risk management according to EN ISO 14971 and IEC 62304
- General knowledge of IVD Directive and IVD Regulation requirements
- Preferably IVD medical device, medical device or pharma work experience
- Experience in providing quality support to regulated manufacturing
- Problem solving and analytical thinking skills
- Detail oriented with excellent organizational and project management skills.
- Strong written and oral communication skills, must be able to communicate effectively with multiple levels of personnel throughout the organization

In return we offer the opportunity to work in a fast-growing dynamic international company that has doubled its personnel in two years. We currently employ 90 people in four countries and want to foster the mix of diversity, enthusiasm and excellent team spirit also in the future. Join our team now and help us to improve the quality and efficiency of healthcare worldwide.

For further information, please contact Director, Quality & Regulatory Timo Soininen by phone +358 40 535 6520 on June 15th at 14:00-16:00 or on June 21st at 13:30-15:30. Please apply by sending your CV and application letter to HR Manager Hanna Osara at hanna.osara@mobidiag.com by June 25th.