

At MEON, we develop, manufacture and market high-quality, modern and innovative medical devices in the field of in vitro diagnostics (IVD) for professional use in clinical laboratories. Our interdisciplinary teams are highly motivated and built on a broad range of technical expertise with a strong technical foundation in domains such as mechanical and electrical engineering, mechatronics, natural sciences (e.g. chemistry, physics, mathematics, life sciences and biomedical analytics) as well as software and firmware.

To guide our team through the regulatory and international registration landscape for IVD devices, we are looking for a

Regulatory Affairs Specialist

What will you do?

- Manage and prepare regulatory submissions with your thorough understanding of EU (IVDR), international regulatory requirements and applicable standards (e.g. IEC EN 62304, IEC EN 61010-1)
- Develop the regulatory strategy for a successful international product launch/roll-out
- Guide the team in the creation of technical files for compliance with CE marking and international registration processes
- Provide high quality, hands-on regulatory support for internal and external stakeholders. E.g. revise technical files, support distributors for local product registration
- Keep up to date with regulatory changes, communicate such changes internally and ensure compliance

What do you bring?

- Strong interest in IVD registration processes
- Basis knowledge of quality management & regulatory affairs (medical devices)
- Initial professional experience (2+ years) in a regulatory role in the IVD industry
- Professional proficiency in English (written /oral), ideally in German as well
- Strong documentation, organizational and communication skills
- Independent and structured way of working

Your education

- University degree (technical university / university of applied science) in biomedical engineering or similar field
- Certification in quality management and/or regulatory affairs is a plus

Our offer

- We offer an interesting, challenging, and technically versatile job with high personal responsibility and opportunity for personal development and advancement within an energetic, highly qualified team which is part of an innovative group of companies with currently ca. 85 colleagues
- We work closely together in a flat hierarchy and develop and produce our products using agile principles
- Appreciative and responsible cooperation is part of our culture
- We manage our working hours in a trust-based flextime working model
- We are easily accessible by public transport
- Dining options are in the immediate vicinity
- The monthly salary depends on your qualification and professional experience and will in any case be above the collectively agreed minimum salary e.g. € 3,895.18 gross * 14 (38.5 hours, 6 years of experience).