careers@ndieurope.com

Be Different. Be Better.

# Regulatory Affairs Specialist

(w/m/d)

- Professionelles Onboarding
- Gute Work-Life-Balance
- Mobiles Arbeiten

**FRAGEN?**

07732 82 34 - 144

www.ndieurope.com

## INSIDE

**Innovation in therapy and diagnosis - that is what we are committed to.**

Leading medical technology companies worldwide rely on our 3D tracking technology – we have been the global market leader in this field for over 20 years. Our expertise as an innovative high-tech company for the realization of modern, digital solutions in medical application fields is a central component of our success.

People work for NDI at four locations worldwide. The cultural diversity in our globally active company and the demands of the high-tech medical industry make for a stimulating work environment. The knowledge, enthusiasm and experience of our employees are essential to our success. And everyone knows everyone by name – including our colleagues in Canada, the USA and Hong Kong. We trust each other, are honest with each other and can celebrate with each other. And we do it across hierarchies – that's what makes work fun!

## TASKS

Do you keep track of complex regulatory requirements and work in a structured and independent manner? Then we look forward to receiving your application! Your tasks:

- Ensuring compliance with regulatory requirements in the area of material compliance (e.g. RoHS, REACH, PFAS) and processing corresponding customer inquiries
- Maintenance and use of relevant databases for material declarations
- Monitoring and implementation of normative requirements (MDR, FDA, ISO 13485)
- Support in quality management, especially in document management, training and CAPA processes
- Review and approval of technical documents as well as support for projects and production inspections

## PROFILE

- Successfully completed technical or scientific studies or comparable training
- Several years of experience in the field of regulatory affairs in medical technology, especially in the area of material compliance
- Very good knowledge of the relevant standards and regulations (ISO 13485, MDR, FDA) and knowledge of quality management are an advantage
- Very good written and spoken German and English skills
- Independent, structured and assertive personality with team spirit and strong communication skills