

# Regulatory Affairs & Compliance Manager Digital (m/f)

Basel

Become part of a creative, inspired and engaged team on a mission. Bring your ideas to life – create your footprint in the dental industry. You can expect an informal, hand-on working environment with opportunities to grow.

## Our Client

Our client is headquartered in Basel, Switzerland. As a global leader in implant, restorative and regenerative dentistry our client shares your passion for quality and the desire to achieve the best restorative outcomes. Our client offers a broad range of products and solutions for both conventional treatment and digital workflows including guided surgery, intra-oral scanning and CAD/CAM restorations.

## Your tasks

- Participate on assigned project (MDR implementation) and product development teams by representing and reinforcing Design Control, Quality Assurance and Regulatory Affairs requirements
- Work in a multidisciplinary group for Technical File adaption according to MDR 2017/745
- Ensure that the technical documentation supporting the CE mark complies with MDD 93/42/EEC
- Create and maintain Technical Files/Design Dossiers
- Create US and Canadian submission dossiers
- Support the International Regulatory Affairs Team in preparation of international Submissions
- Interaction with authorities, notified bodies and any other approving bodies that will be relevant
- Assessment of potential risks and the classification of the medical device in accordance with MDD and MDR
- Support and consultation of the Departments in regard of interpretation of regulatory rules/laws/guidelines
- Identify and communicate potential risks in submission and anticipate regulatory responses through scenario planning

## Your profile

- BSc or MSc degree in a technical or natural scientific field
- At least two years professional experience in Regulatory Affairs and/or Quality Management
- Knowledge about the standards and directives for Medical Devices such as ISO 13485, ISO 14971, MDD 93/42/EEC and MDR 2017/745
- Experience from Audits would be a plus
- Fluency in English (in writing and speaking), further knowledge of additional languages e.g. German would be an asset
- Customer-driven, solution-focused, systems-oriented and emotionally intelligent personality
- Advanced knowledge of excel and data analysis would be a plus