ANTERIS MEDICAL

anteris medical has been founded in 2014 and supports medical device product development and compliance projects in the medical device and pharma/biotech industries. In particular, we help new entrants into the exploding Biosimilars market to enable the success of their products with compliant development of the right medical devices or medical device components in a combination product, both in the US and the EU.

For the strengthening of our team at **our location in the Munich area** we are currently looking for a

SENIOR DEVICE DEVELOPMENT MANAGER (f/m/d)

YOUR KEY RESPONSIBILITIES

- Project Management of Device and Combination Product Projects for our customers
- Preparation of development, quality and regulatory documents in compliance with regulatory standards
- Developing/compiling Technical Files and Design Dossiers
- Strategic planning and preparation of regulatory submission documents, interpretation of regulations and compliance with regulatory guidance
- Driving risk management activities during development and post-launch
- Performing design validation activities, e.g. planning, execution and reporting of Human Factors studies
- Consulting with customers regarding quality management and quality control challenges
- Auditing according to EN ISO 13485 and CFR 820

YOUR BENEFITS

- Working for and being part of a fast-growing organization
- Work with a high degree of responsibility and independence
- Flexibility in terms of working hours and work place
- The time spent in our offices will be in a suburban setting close to lakes and mountains, yet a stone-throw away from Munich (connected by public transportation and highway)
- Work in a landscape, where other people take their vacation
- Work on attractive and varying projects in different geographies for different clients
- Be part of an emerging organization in the explosive growth of the Biosimilar market
- Attractive, performance-based compensation package

YOUR PROFILE

- Bachelor / Master in engineering or life sciences or with an equivalent combination of qualification and experience
- Experience in pharma or biotech organization is a plus
- Knowledge of regulatory guidelines: Medical Device Directive and Regulation (MDD & MDR) –CFR 820, EN ISO 13485 and EN ISO 14971,
- Ideally with experience in the field of medical devices of at least 3 years (Bachelor) or 5 years (Master) or similar
- Client-focused approach to work
- Excellent communication skills (verbally and in writing)
- Ability to work independently, take initiative, and have a flexible approach with respect to work assignments and training needs
- Analytic and business-oriented thinking
- Ability to travel locally and internationally, as required
- Ability to work at the client's site, as required
- Excellent command of English and German
- Driver's license

Your contact for this position:

Dr. Michael Gschwandtner (mg@anteris-medical.com)

Please send your comprehensive resume including earliest possible starting date.

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