

Looking to make your mark? Then consider regenold GmbH!

We are looking for a

Regulatory Affairs Expert (m/f/d) in Active Medical Device Software

Who we are and what we do

Founded in 1994, regenold GmbH is an international regulatory service provider with over 100 employees. We support clients worldwide in the development, approval and market access of pharmaceuticals, medical devices and in vitro diagnostics, cosmetics, food supplements and other healthcare products. *You can find more information on our homepage: www.regenold.com*

Your field of activity

- Advice on and compilation of Technical Documentations, in particular with a focus on software as a medical device or devices with embedded software
- Compliance and implementation of regulatory requirements according to MDR 2017/745 and/or 2017/746 as well as the older directives MDD, IVD and AIMD
- Close cooperation with national and international customers, as well as with Notified Bodies and Competent Authorities
- Development of creative, customised solutions in order to fulfill client needs combined with regulatory requirements
- Customer relationship management and engagement management
- Internal process and method optimisation

Ideally, you should have the following skills and knowledge

- A background in in computer science or comparable qualifications in the field of software
- Deep knowledge of the software lifecycle process, ideally according to IEC 62304, e.g., software requirements analysis, software architecture, detailed software design, testing, data protection concepts, medical cloud, software risk management
- Excellent project management skills
- Fluent written and oral communication skills in German and English
- Ideally experience in other relevant standards such as ISO 14971, IEC 62366 or optionally IEC 60601-x

What makes us tick

- Customer and solution orientation - for us, this is the DNA of a good service provider
- Experience, expertise and worldwide networking in over 90 countries through the regulanet® network, www.regulanet.com
- Innovative and long-standing customers who are happy to recommend us to others
- A family-like and personal team spirit in a modern working environment

What we offer

- International diversity - in the team and in the projects
- Long-term prospects – for professional and personal development, we offer a wide range of tasks and individually tailored training opportunities right from the onboarding phase
- Flexibility, freedom and personal responsibility - through flat hierarchies, short decision-making processes and family-friendly working time models, with something for everyone
- One of the most beautiful regions in Germany, on the edge of the Black Forest in the border triangle of Germany, France and Switzerland
- Attractive salary, company pension scheme, capital-forming benefits, JOBRAD and much more...



Have we made you curious? Could you fit in with us?

Then we look forward to receiving your completed application at perspectives@regenold.com.

Your contact person is: Christine von der Brelie, +49 (7632) 8226-410.

regenold GmbH, Zöllinplatz 4, 79410 Badenweiler, www.regenold.com