

Looking to make your mark? Then consider regenold GmbH!

We are looking for a

Regulatory Affairs Expert (m/f/d) in in-vitro diagnostic medical devices

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

- Development and implementation of custom-tailored solutions to fulfill EU regulatory requirements (IVDR 2017/746, ISO 13485:2016, etc.)
- Compilation of Technical Documentations for a diverse landscape of products, technologies and indications
- Implementation of Quality Management Systems (EN ISO 13458:2016, MDSAP, etc.)
- Close interaction with international clients as well as Notified Bodies and Competent Authorities

Ideally, you should have the following skills and knowledge

- A background in natural sciences, med tech, engineering or equivalent
- Experience (3y+) in IVD regulatory affairs and/or quality management related positions in the IVD industry or at a Notified Body / Competent Authority
- Sound knowledge in CE-marking of IVD products (preferably reagents / reagent kits)
- Sound knowledge in Quality Management Systems (EN ISO 13485:2016)
- Very good written and spoken German and English skills

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, JOBRAID, HANSEFIT 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.

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