Looking to make your mark?
Then consider CE plus!

We are looking for a

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

Who we are and what we do
CE plus is a division of regenold GmbH - an international regulatory service provider specialized in pharmaceuticals, medical devices, cosmetics, food supplements and other healthcare products. The core activities of CE plus comprise regulatory services for medical devices and in vitro diagnostics, and our key competence is CE-marking for the European market. Through close collaboration with experts from regenold GmbH, we are also able to offer a wide range of related services.
You can find more information on our homepage: www.ceplus.eu

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
- In addition, attractive salary, company pension scheme, capital-forming benefits, JOBRAD, joint hikes with children, kids and family dog, joint Christmas party...

Your field of activity
- Ensure fulfillment of EU requirements (IVDD 98/79/EC, IVDR 2017/746)
- Compilation of Technical Documentations
- A diverse landscape of customers, products, and technologies
- Interactive collaboration with in-house experts covering all subjects related to CE-marking of IVDs (preclinical experts, clinicians, QM experts, etc.)
- Implementation of quality management systems, e.g., according to EN ISO 13458:2016 or MDSAP
- Close interaction with international clients as well as Notified Bodies and Competent Authorities
- Development of creative solutions to fulfill client needs combined with regulatory requirements

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
- CE-marking of IVD products (preferably reagents / reagent kits)
- Quality management systems (EN ISO 13485:2016)
- Very good written and spoken German and English skills

CE plus
MEDICAL DEVICES | IVD
Regulatory Affairs & 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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