

# Looking to make your mark? Then consider CE plus!

We are looking for a

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

### 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](http://www.ceplus.eu)

### 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 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](http://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 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](mailto:perspectives@regenold.com).

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

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