Looking to make your mark?
Then consider CE plus!

We are looking for a

Team lead Active Medical Devices (m/f/d)

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
- Leadership of the Active Medical Devices Team of currently 3 people, with a special focus on the strategic development of the team and the design of efficient processes and methods
- Compilation of Technical Documentations
- Ensure fulfillment of EU requirements (93/42/EEC, 98/79/EC, 90/385/EEC) as well as new EU regulations 2017/745 und 2017/746
- Interactive collaboration with In-house experts covering all subjects related to CE-marking of medical devices /IVDs (preclinicians, clinicians, QM etc.) Implement and maintain regulatory SOPs within ISO 13485
- Close interaction with international clients as well as Notified Bodies and Competent Authorities
- Development of creative solutions in order to fulfill client needs combined with regulatory requirements

Ideally, you should have the following skills and knowledge
- A background in software engineering and several years of professional and management experience in a comparable position
- Experience with key topics of a software development lifecycle, such as software requirement analysis, software architecture, detailed software design, testing (Modul, Integration, System), maintenance
- Very good knowledge of IEC 62304
- Excellent project management skills
- fluent written and oral communication skills in German and English

Preferable but not mandatory:
- Practical experience in CE-marking of software
- Experience with international registrations such as 510(k)
- Knowledge in IEC 60601-x and closely related standards, such as ISO 14971 or IEC 62366
- Experience in medical device or IVD industry, preferably in regulatory affairs and/or quality management related positions; Notified Body experience

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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