Looking to make your mark?
Then consider CE plus!

We are looking for a

Regulatory Affairs Expert (m/f/d) in Medical Devices focusing on biocompatibility according to ISO 10993

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

- Compiling scientific statements on the biocompatibility of medical devices in a regulated environment, e.g. EN ISO 10993 standard series
- Meeting the EU requirements according to MDR (EU) 2017/745 with a focus on biocompatibility as part of the risk management process
- Developing scientifically creative solutions to meet customer needs in conjunction with regulatory requirements

Ideally, you should have the following skills and knowledge

- Educated in the fields of natural sciences, preferably life sciences including pharmaceutical sciences, medical technology, or comparable educational background
- Sound knowledge in the preparation of scientific documentation on chemical and/or biological topics, preferably with regard to the mode of action of substance-based medical devices
- Very good knowledge in chemical, physical, biological and/or toxicological characterisation of materials, formulations (including cosmetic or pharmaceutical) and/or medical devices
- Experienced in literature search and application of literature databases and also in bioanalytics and validation of bioanalytical methods
- Experience in risk management preferably in a medical device environment (ISO 14971) and in the medical device industry, preferably in positions in Research & Development, Regulatory/Scientific/Clinical Affairs or Notified Bodies
- 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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