Job Title	Regulatory Affairs Expert in in-vitro diagnostic medical devices (m/f/d)
Position Type	Full time position

Job Description

Who are we?

CE plus GmbH specializes in international regulatory affairs for medical devices and in vitro diagnostics. The spirit of partnership is important to us - in our relationships with our clients and partners as well as in the relationships among the individuals working with CEplus. Our business culture is based on open communication and on a structure that accommodates each individual's knowledge and skills. As an ambitious and progressive independent Regulatory Affairs service provider, we offer the opportunity for an IVD expert to join our team based in Southern Germany near Basel (Badenweiler).

Find out more about CEplus: www.ceplus.eu

What we offer:

As a regulatory affairs expert (m/f/d) on in-vitro diagnostic (IVD) medical devices you will focus on the regulatory support of IVD and companion diagnostic (CDx) products throughout the entire product lifecycle. You will have the opportunity to work on a variety of different projects within our CEplus team and you will be involved in various tasks, such as:

- 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.

Skills/Qualifications:

- 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)
- Preferable but not mandatory – practical experience in:
    - List A / B products (future class C/D products)
    - Analytical performance evaluation (e.g., CLSI)
    - Clinical performance evaluation
- Excellent project management skills
- Confident appearance with customers
- Good written and oral communication skills in English and German

Are you interested?

If you possess above mentioned skills please send your application including cover letter, curriculum vitae, and references to our human resources team at **perspectives@ceplus.eu**