Job Title	Medical Device Expert (m/f/d) for substance-based medical devices
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 Medical Device Expert with a special focus on substance based medical devices to join our team based in Southern Germany near Basel (Badenweiler). Find out more about CEplus: www.ceplus.eu

What we offer:

As an experienced Medical Device Expert (m/f/d) for substance-based medical devices, you will focus on regulatory support for medical devices throughout the entire product life cycle and will be involved in a variety of projects and tasks, such as

- Development of tailor-made solutions and/or strategies for the approval of substance-based medical devices in accordance with MDR 2017/745 Annex I
- Development - technical and regulatory - of substance-based medical devices, ideally with knowledge of pharmaceutical and/or cosmetic formulation(s)
- Preparation of technical documentation for the medical device part of a substance-based medical device according to Annex II/III
- Evaluation/assessment of customer documentation with a focus on the general safety requirements, Annex I MDR
- Interactive collaboration with in-house experts on all topics related to CE marking of medical devices (pre-clinicians, clinicians, QM experts, etc.)

Skills/Qualifications:

- Completed education in the field of pharmaceutical or medical technology or comparable educational background
- Sound knowledge and experience with the regulatory basis defined by the MDR (EU) 2017/745, in particular for the regulation of substance-based medical devices
- Experience in writing CTD Module 3 and 2.3 in the context of pharmaceutical marketing authorizations or (PIF) Product Information Files for cosmetics
- Experience in the medical device industry, preferably in positions in Research and Development, Regulatory/Scientific Affairs or Notified Bodies
- Very good written and spoken German and English skills
- Proven project management skills
- High level of teamwork and communication skills

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**