Job Title	Regulatory Affairs Expert in Software as a Medical Device (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 - not only in our relationships with our clients and partners but also in the relationships among the individuals who work for 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 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 in Software as a Medical Device (m/f/d) you will focus on the regulatory support of medical device / IVD software throughout the entire product lifecycle. You will also 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:

- 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

Skills/Qualifications:

- A background in software engineering
- 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

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