Job opportunity

Regulatory Consultant - Medical Devices

Job description

We offer a job as a **Regulatory Consultant – Medical Devices**, in which you will:

- optimally combine your scientific background and regulatory knowledge
- work in an international environment of pharmaceutical and medical device/in vitro diagnostics industry
- prepare and update technical documentation (eg. PSUR, BSER, CER, RMP) for applications
- coordinate and manage authorisation procedures and interactions with notified bodies
- implement and maintain ISO 13485 QMS
- perform IVD and medical device directive vs. regulation gap analysis
- be coached by Zwiers-live up to the Zwiers "professional approach with a personal touch" spirit

Profile

You have:

- an MSc/PhD in Pharmacy, Medical Biology, Chemistry, Life Sciences
- 2-3 years of experience in the medical device/IVD industry, preferable RA/QA
- knowledge of ISO standards
- prefeably, audit experience
- the eagerness to learn, develop and excel
- a flexible and pragmatic personality
- the ability to handle stringent deadlines
- writing and editing skills (English)
- the ability to communicate in a convincing way

Offer

Zwiers Regulatory Consultancy offers a fulltime job, but is willing to discuss a part time contract
Salary will depend on education, knowledge and experience

Contact

For further information you can contact Alex Zwiers, CEO, at tel. +31 (0) 6 344 848 51.
We look forward to your application. You can apply via email: info@az-regulatory.com