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
- 2-5 years of experience in the medical device/IVD industry, preferable RA/QA
- knowledge of ISO standards
- preferably, 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 Tom Manussen, Director at tel. 0031 643629005. We look forward to your application. You can apply via email: info@az-regulatory.com