Job opportunity

Experienced Regulatory Consultant - Medical Devices

ZWIERS Regulatory Consultancy

Job description

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

- optimally combine your scientific background and regulatory knowledge
- have a dynamic strategic position in innovative medical device development and life cycle
- write and update technical documentation (e.g. PMSR/PSUR, BER, CER, RMR) for applications
- define, write and action regulatory strategy plans
- interact with notified bodies and authorities
- implement and maintain ISO 13485 quality management system
- perform gap analyses
- be coached by Zwiers and live up to the Zwiers "professional approach with a personal touch" spirit

Profile

You have:

- an MSc/PhD in Life Sciences, Medical Biology, Chemistry, Pharmacy
- at least 7 years of experience in Development & Regulatory Affairs in Medical Device industry
- in depth knowledge & understanding of the MDR & ISO standards
- preferably, FDA knowledge and experience
- 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