SENIOR REGULATORY AFFAIRS SPECIALIST - AIMD DEVICES

Basel, Switzerland

Want to work for a company that truly changes lives?

Our client is a big player in the Active Implantable Medical Device field. The device is known around the world, for the huge patient benefit it brings.

The Company

With an excellent work life balance, low staff turnover, and ideal location in central Basel, this role will make you want to wake up and go to work everyday, feeling proud to say that your work really makes a difference.

This is a great opportunity to work on a product that is at the cutting edge of regulation, and highly innovative. Learn about software, hardware, accessories, biocompatibility – and more!

The Regulatory Affairs specialist will report to the Director RA EMEA and form part of a small, yet dynamic team. The activities are broad, ranging from supporting development projects to responding to Notified bodies.

You will not just be a “postbox” for registrations! This is a great chance to be part of a growing regulatory team, as its importance increases within the business (thanks MDR!). Looking to the future, this company offers lots of opportunity for career development and training.

Employees have enjoyed attending conferences, assignments and secondments, both locally and in the company’s HQ on the other side of the world!

Key Responsibilities

- Authoring and preparing regulatory submissions, and having discussions with competent authorities throughout Europe
- Supporting with post market activities
- Supporting with extra – EU submission as the regulations in individual countries become more stringent
- Ensuring licenses and registrations are maintained in the region
- Advising marketing on claims and promotional material, representing regulatory to internal and external stakeholders
- Consistently working to ensure high level of continuous improvement for all regulatory processes

Requirements

- 2.5+ years experience in a regulatory role in the medical device industry
- Proven RA experience: Minimum successful CE marking
- Experience with class IIB or class III
- medical devices
- Someone who takes initiative, is hands-on, proactive

CONTACT US:
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