READY FOR A NEW CHALLENGE?

SENIOR MANAGER QUALITY MANAGEMENT& REGULATORY AFFAIRS

Zurich, Switzerland

JOIN A WELL ESTABLISHED, START-UP COMPANY DESIGNING, DEVELOPING AND PRODUCING A CLASS III

ACTIVE IMPLANTABLE MEDICAL DEVICE
THAT CHANGES THE LIVES OF PATIENTS

THE CHALLENGE

Join a well established, start-up company designing, developing and producing a Class III active implantable medical device that changes the lives of patients. The device is CE marked, and recently submitted for US approval. With a strong KOL network in Europe and North America the company are looking for a hands-on Senior Manager Regulatory Affairs and Quality Management.

The goal: to drive and implement the regulatory and quality management strategy for the business. This is a great opportunity to work on an AIMD that has no predicate (making it unique and challenging!), have great exposure to the senior leadership team (you will report to the VP Quality / Regulatory, and impact the business direction.

If you are looking for a role with a large team to manage, this position is not for you. This role is all about being hands on with the product and working in a tight knit team with one vision, surrounded by other senior experts in their field.

You can be sure that no two days will be the same! You'll enjoy a wide variety of responsibilities covering various elements of Regulatory and Quality management, fast moving

Swipe for responsibilities>>

IN THIS ROLE YOU WILL:

Develop, implement and maintain the program for quality management and regulatory affairs activities for the company.
Drive and execute regulatory submissions and manage questions and responses to Notified Bodies and Health Authorities including FDA
Evaluate design and process changes to determine the impact on regulatory compliance and submissions
Manage and maintain the QMS and necessary SOPs
Drive key relationships with the Notified Body, FDA and other external stakeholders
Review/approve promotional material
Guide the transition to the new MDR.

Collaborate and coach other departments (in particular R&D) on product development projects with regards to Electrical safety, Usability and Software topics.

Conducting internal and supplier audits and participating in external audits (travel is 10-15%)
Supporting and acting as deputy to the VP Quality Regulatory
(not an exhaustive list)

IS THIS YOU...?

5+ years experience in RA/QM in the medical device industry
Strong experience in Regulatory Affairs with Active (electrical) medical devices.
Class III or AIMD experience is not required, but if you have the necessary
background with active devices, a willingness to learn about AIMD and class III is essential! CE Marking
Fluent written and spoken English
Adaptable, reliable and independent

GET IN TOUCH

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