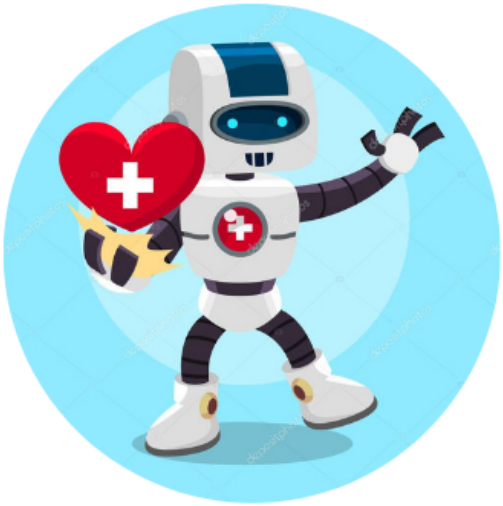
REGULATORY AFFAIRS SPECIALIST

ACTIVE MEDICAL DEVICES



Zurich, Switzerland

THE COMPANY

OUR CLIENT IS A WORLD LEADER IN HIGH RISK NON-ACTIVE MEDICAL DEVICES. THEY HAVE CREATED A GROUNDBREAKING NEW PRODUCT PORTFOLIO FOCUSSING ON ELECTRICAL MEDICAL DEVICES!

WE ARE LOOKING FOR A SENIOR RA EXPERT TO LEAD REGULATORY IN NEW PRODUCT DEVELOPMENT PROJECTS AND PROVIDE GUIDANCE ON ACTIVE MEDICAL TECHNOLOGY. YOU WILL LEAD THE COMPLETE LIFECYCLE OF YOUR VERY OWN DEVICE PORTFOLIO OF ELECTRICAL MEDICAL DEVICES.

The Opportunity

Are you passionate about handling the complete lifecycle?
You will be responsible for: New product device development, Post market and Compliance in this far-reaching role.

- **Represent regulatory on product development projects, leading the RA strategy**
- **Provide guidance on the approval process through the EU, US and other markets for active devices**
- **Foster relationships with the Notified body. Respond to compliance questions as the expert on electrical devices**
- **Support the post market surveillance team as the subject matter lead for your products**
- **Participate in product registrations to international competent authorities for your device portfolio**
- **Audit suppliers periodically to ensure compliance with Regulatory (RA) topics**

Are you looking for the opportunity to share your Regulatory affairs expertise with others? We believe that someone motivated, by an open and collaborative environment would be perfect for this role. If you fit these requirements, we want to hear from you!

- **4+ years RA experience**
- **Expertise with active medical devices: IEC 60601-XX**
- **Engineering technical background**
- **IEC 62304 (software standard knowledge is a benefit)**

Please send your CV to hello@elemed.eu to arrange a confidential career discussion.