Senior Regulatory Affairs Specialist

Solothurn Area, Switzerland

THE COMPANY

Are you a regulatory superhero? This company has been voted over and over again to be one of the best employers in Medtech!

With one of the highest employee satisfaction and retention rates in Switzerland, this company offers security, stability and long term career opportunities.

This position is all about supporting product development projects to deliver regulatory strategy across Europe, the US and internationally. The products are implants, class III, and even some combination products!

THE ROLE

Owing to a recent acquisition and big pipeline of product development, a new role has been created. This is a great chance to be part of something that you can shape yourself, not having to fit into someone else's shoes!

As Senior Regulatory Specialist:

- Be responsible for ensuring compliance to EU, US and international regulations, for your portfolio of medical devices
- Work together with the FDA, Notified bodies and other regulators to ensure regulatory approval
- Author 510(k) submissions for regulatory approval in the US markets
- Follow the development of high risk medical devices, from concept to market approval, i.e cradle to grave
- Support other partners from the company as the subject matter expert for your own portfolio of medical devices
- Work on cross functional teams; R&D, marketing and manufacturing to advise the regulatory impact of proposed product changes and transfers

DO YOU HAVE ...

- 2 - 6 years experience in Regulatory affairs with medical devices?
- Experience with a minimum class IIb products?
- Fluent English?

PLEASE CONTACT HELLO@ELEMED.EU FOR A CONFIDENTIAL CAREER DISCUSSION.