



REGULATORY AFFAIRS SPECIALIST

ZURICH, SWITZERLAND

The Company

Are you passionate about the product?

Join a privately held medical device company, where the focus is on the patients, not the share holders! An exciting opportunity to work on brand new class III products in development projects.

From cradle to grave, concept to market! A highly rewarding role, to create something new. We are looking for a real “specialist” to lead complicated regulatory projects for high risk, class III devices, and combination devices globally.

This is a senior position amongst the team, and this person will be expected to set an example of excellence for RA project management to the junior members of the team.

REGULATORY AFFAIRS SENIOR SPECIALIST RESPONSIBILITIES

- Represent regulatory affairs (RA) in complex product development projects, ensuring compliance to the current MDD and expected MDR
- Develop and execute the RA strategy for brand new product introduction (NPI) in global regulatory markets: USA, CE, Japan etc.
- Managing requests and responses to notified bodies and authorities
- Maintain regulatory documentation for worldwide use

Essential Requirements

- CE marking
- Proven RA experience and exposure in NPD projects - working with design controls
- Only medical device experience will be considered for this role



Apply now:

hello@elemed.eu