SENIOR RA SPECIALIST

Zurich, Switzerland

THE COMPANY

Located near to Zurich, this medical device is a world player, and you'll have the chance to be at the hub of everything going on - in the EMEA HQ! Enjoy a great challenge in this RA senior specialist position, where teamwork, sharing of ideas and enjoying what you do is key.

We are looking for a real "specialist" to lead complicated regulatory projects for high risk, class III devices. This is a senior position amongst the team, and this person will be expected to set an example of excellence for Regulatory activities to the junior members of the team.This is a role that covers a little bit of everything relating to your product portfolio; New product development, changes, maintenance, NPI and Medical device Regulation (MDR). You will have no concerns about the future and stability of this company as their EU MDR preparation is well underway. They already have invested a significant amount in the EU MDR readiness program!

The opportunity:

- Full lifecycle management of an implant portfolio of medical devices across multiple regions including major markets (EMEA, USA)
- Be the Regulatory lead in exciting New Product Development Projects, and work alongside Marketing, Quality, R&D to devise the regulatory strategy for new product launch and product modifications
- Managing requests and responses to notified bodies and authorities
- Be responsible for the maintenance of regulatory documentation for worldwide use
- Support the MDR transition and its impact on your particular portfolio

Essential Requirements:

- Minimum 3 years experience in premarket regulatory activities in the Medical device industry
- Experience with CE Marking or 510k submissions
- Regulatory experience with medical devices class IIb or above

We'd love to hear from you! Please send your CV to elena@elemed.eu to arrange a confidential career discussion.