EU MDR

REGULATORY SPECIALIST

Solothurn, Switzerland

ARE YOU LOOKING TO JOIN A COMPANY WITH OPEN COMMUNICATION, POSITIVITY AND AN EXCELLENT SOCIAL ENVIRONMENT?

LOOK NO FURTHER! THIS IS AN OUTSTANDING OPPORTUNITY TO JOIN A WORLD LEADING MEDTECH COMPANY THAT HAS BEEN RECOGNISED TO BE ONE OF THE TOP EMPLOYERS IN MEDICAL DEVICES. THIS IS A BRAND NEW POSITION FOCUSSED ON IMPLEMENTING THE NEW MDR FOR A WIDE RANGE OF DEVICES (CLASS I-III), FOCUSING ON TRAUMA AND EXTREMITIES.

THE OPPORTUNITY:

You will be supporting and implementing the new MDR project, working in a multidisciplinary project team of around 35 people, from quality, R&D, medical and engineering departments across 3 different countries. But there is life after MDR! Once the MDR transition has been successfully completed, the role will transform into a senior RA specialist, giving you an opportunity to work on new product development projects.

YOUR RESPONSIBILITIES WILL INCLUDE:

- Support and guide the new EU MDR implementation project
- Advise, guide and train R&D, marketing and manufacturing teams on the new EU Medical Device Regulation
- Communicate with the Notified Bodies, FDA and other regulatory agencies on approvals and submissions
- Organise and implement strategies to obtain RA approval for new and revised devices
- Ensuring compliance to all US, EU and international requirements for market approval
- Participating in cross functional team activities through securing government approvals that require RA support
- Applying scientific principles to products to assure safety and efficiency

>>> Swipe up

Essential requirements:

- Bachelor's degree in scientific discipline
- Minimum 5+ years experience in regulatory affairs for medical devices

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