



REGULATORY AFFAIRS SPECIALIST

Remote in Europe

Duration: 4 months
Start: as soon as possible

If you are interested,
contact Monia at
monia@elemed.eu



THE COMPANY

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 focused on implementing the new MDR for a wide range of devices (class I-III), focusing on trauma and extremities

ESSENTIAL REQUIREMENT:

1

Bachelor's degree in scientific discipline

2

Minimum 2+ years experience in regulatory affairs for medical devices

YOUR MISSION AS REGULATORY AFFAIRS SPECIALIST

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 project

YOUR RESPONSIBILITIES AS REGULATORY AFFAIRS SPECIALIST

- Support in keeping business continuity in terms of New Products registration documentation support to our Distributors and Direct countries.
- Keep track and metrics on countries submissions, approvals and renewals.
- Support NV Indirect Channels (IC) Intake (review and maintain RA/QA filings).
- Feedback to RA management on RA intel on change in regulatory environment (special focus on Brexit, EEU, Switzerland, Turkey, etc.).



If you are interested in this exciting role, please send your application directly to monia@elemedeu