

Job Offer: Regulatory Affairs Officer – Medical Devices

Purpose of the role:

We are looking for a Regulatory Affairs Officer - Medical devices with experience within pharmaceutical industry to join our team, someone who loves to take new challenges, to work in an international environment and who wants to grow with us.

Job functions:

The Regulatory Affairs Officer – Medical devices will be in charge of the timely and correct execution of projects according to defined timelines:

- Work with direct reports to develop successful global regulatory strategies to ensure timely device approvals: roadmaps, viability analysis, clinical evaluation, risk management
- Guide clients in decisions concerning medical device product development and promotion
- Collect and coordinate information and prepare regulatory documentation for submission to different regions worldwide (EU, USA, etc.): technical file preparation & review (CE marking), FDA clearance (510(k)) and premarket approval (PMA)
- Communication with notified bodies
- Business development and marketing activities
- Establishing processes and working instructions
- Provide direct supervision of team including mentoring, training and performance management

Requirements:

- Scientific or engineering academic background
- +2 years experience in Regulatory Affairs – Medical devices (experience in EU & FDA)
- Fluent English & Spanish
- Proactive, good communication, negotiation and follow up of potential clients.

We offer you:

- Great colleagues!
- Opportunities for professional and personal development.
- A position with challenging tasks and flexible working schedule
- An organization with highly professional people to develop with
- An international organization – More than 12 nationalities!
- A growing organization with ambitious target

If you are interested please send us your CV to rrhh@asphalion.com with the subject “**Job Offer: Regulatory Affairs Officer – Medical Devices**”

We also advise you to follow us in LinkedIn to check for new careers opportunities:

https://www.linkedin.com/jobs/search/?f_C=924722&locationId=OTHERS.worldwide