Hybrid - Barcelona, Spain

REGIONAL QARA SPECIALIST

frankie@elemed.eu

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THE COMPANY

Are you someone who has IBERIAN-wide regulatory experiences and is looking for the next step in your Regulatory career in the medical devices industry at the EMEA level? Are you someone who likes to be in touch with surgeons? Do you see yourself joining an established, medium-sized company where there are constantly new product innovations and strong investments in the Regulatory and Quality department? And are you looking for a hybrid role?

Here is a rare and great opportunity to join an international leader in surgical technology be part of this company's IBERIAN growth strategy and be visible at the EMEA level. As the Regional QARA Specialist for the IBERIAN region, you will be based at their Spain branch office in Barcelona, where they have centralised sales, marketing, and customer success teams all in one place.

THE COMPANY

This is a company-critical role and your past experiences in registrations can help the company to reach their business goals for the EMEA region.

This exciting position will give you the opportunity to work in a diverse international environment.

You will be responsible for the quality system of the sales office in Barcelona as well as supporting the registrations for Spain. Furthermore, you are part of the EMEA Quality Assurance and Regulatory Affairs team, for this region, you will be responsible for collecting clinical data from surgeons to assist the HQ in the US with clinical surveillance.

In this role, you will report directly to the Sr Director of Quality Assurance and Regulatory Affairs International.

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RESPONSIBILITIES

As the Regional QARA Specialist for IBERIAN, you will:

- Maintain the Quality Management System for their Spanish Organisation
- Prepare and lead the quality management review meetings
- Training and coaching people on the procedures and processes
- Identify local regulatory requirements and lead impact assessment which is driving quality management system changes
- Execute Local regulatory registrations where necessary
- Supporting internal and external audits
- Leading clinical data collection for submission and PMCF
- EMEA regulatory affairs activities concerning importer and authorised representative requirements

REQUIREMENTS

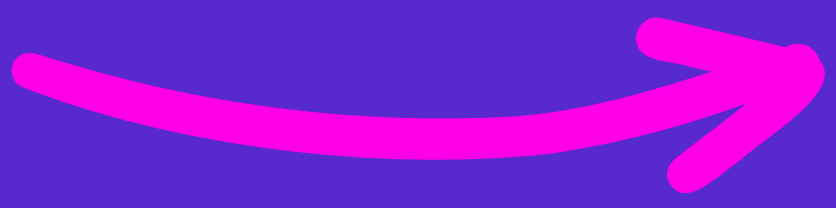
For this Regional QARA Specialist, you will bring:

- At least 3 years in a quality assurance or regulatory affairs role
- Experience within either the medical device or Pharma industry is required
- Fluent in written & and spoken Spanish and English
- Office-presence 3 days per week in Barcelona

GET IN TOUCH

Interested to explore this further? Please send your CV to **frankie@elemed.eu** to arrange a confidential career discussion.

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/



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