REGULATORY AFFAIRS SPECIALIST (EMEA)

DUBAI (UAE)

monia@elemed.eu

elemed

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 recognised as one of the top employers in medical devices.

This is a position focused on EMEA registrations!

The opportunity

You will be supporting and implementing EMEA registrations, working in a multidisciplinary project team across different countries.

This will be your chance to be part of an emerging market that offers a lot of updates!

The responsibilities

- Identifies information sources and resources for local, regional, and global regulations
- Collects, organizes and maintains files on local, regional, and global regulatory intelligence and other related information
- Monitors the regulatory environment (specific regulations, guidance and other relevant information by product types, geography, etc.)
- Provides information used to evaluate proposed products for regulatory classification and jurisdiction
- Researches requirements (local, national, international), applicable guidance and standards and options for regulatory submissions, approval pathways, and compliance activities
- Assists in the development of regulatory procedures
- Collects and organizes information on requirements for regulatory, quality, preclinical, and clinical data to meet applicable regulations
- Compiles and organizes materials for pre-submission reports and communications
- Assists in the preparation of dossiers and pre-submission and submission packages for regulatory agencies
- Tracks the status of applications under regulatory review and provides updates to the regulatory team
- Maintains logs of communication and outcomes with regulators and other relevant internal or external stakeholders
- Assists in the scheduling of meetings with internal stakeholders and regulators and develop and organizes materials for these meetings

The requirements

- Bachelor in Engineering, Science, or related degree; or Master Degree in Regulatory Science
- 1 year of experience in Regulatory Affairs within the Medical Devices Industry
- Speaks fluently English

Get in touch

If you are interested in this exciting role, please send your application directly to **monia@elemed.eu**

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