Regulatory Affairs Specialist

Lausanne, Switzerland

monia@elemed.eu

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The company

Are you looking to join a company that is both flexible and modern?

You will be based in the heart of the company's EMEA headquarters. With offices overlooking the beautiful city of Lausanne, and offering spectacular views of the nearby Alps, you can truly enjoy a great working environment and lots of face-to-face contact with your partners. This company is unique. A well-known leader in its field, with medical device AND (famous!) consumer brands, the environment is fast-paced, collaborative, and dynamic.

You will report to the QMS & Regulatory Affairs Manager EMEA who is supportive and a great expert in the field. You will gain excellent training and coaching, providing a fantastic platform for you to develop your career across a diverse product range.

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The opportunity

This position is a permanent position starting as soon as possible. This opportunity will allow you to work on all the regulatory activities from A to Z and have a big overview of all the processes!

You will be working primarily on the medical device brands' products and will be able to extend your skills and knowledge to other industries such as Consumer Goods. You will be included in all training for the medical device product line. Thus a great opportunity to expand your skills in multiple highly regulated industries.

As the regulatory affairs specialist, your responsibilities will include (70% medical devices / 20% home products, and 10% QMS):

- Maintain regulatory documentation up to date for EMEA regulatory purposes
- Follow Post Market Surveillance activities including complaint reporting
- Being in charge of MDR transition and Technical Documentation
- Review labeling
- Participate during notified body audit and other inspections

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The responsibilities

For medical devices (MD):

- Maintain regulatory documentation up to date for EMEA regulatory purposes
- Prepare documentation dossiers to achieve timely regulatory approvals and maintenance of the existing portfolio
- Being in charge of all aspects of Technical Documentation (MDR 2017/745) for specific projects (NPDs and changes)
- Being in charge of MDR transition for the specific projects the person is working on (legacy devices)
- Work closely with product development, marketing and other teams to ensure and maintain compliance for all categories of products
- Follow Post Market Surveillance activities including complaint reporting
- Follow Clinical Evaluation elements
- Are responsible for the implementation of regulatory aspects of labelling

For wellness products:

- Work closely with product development, marketing and other teams to ensure and maintain compliance for all categories of products
- Maintain regulatory documentation up to date for EMEA regulatory purposes
- Review all applicable test reports and ensure they are all up-to-date, applicable and sufficient
- Review initial release and changes for manager approval
- Prepare and maintain EU Declaration of Compliance / EU Declaration of Conformity
- Are responsible for the implementation of regulatory aspects of labelling

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The responsibilities

Participate in QMS maintenance for MD:

- Propose improvements to ensure/maintain compliance with regulatory standards
- Participate during notified body audit and other inspections
- Support Post-Market Surveillance activities including complaint reporting for MD

Qualifications

- University or engineering degree in Regulatory Affairs within Medical Devices
- Or firsthand experience in RA within MD
- Fluent in English (spoken and written), French is a plus

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

monia@elemed.eu

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