WE ARE LOOKING FOR YOU!

REGULATORY AFFAIRS SPECIALIST

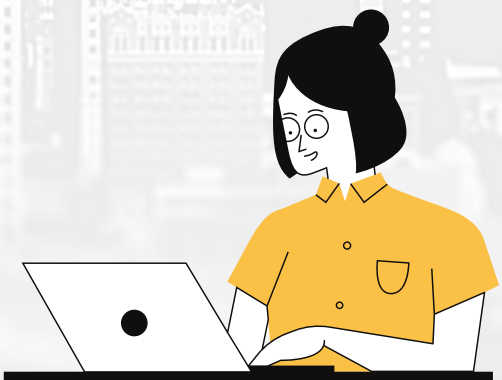
Friesland, Netherlands

THE COMPANY

Do you want to be part of one of the world's biggest healthcare companies? With an extremely dynamic growth strategy, and great future prospects, this is for sure a company where you won't get bored!
Come and join one of the world's biggest healthcare companies whose new ideas are transforming the future! With 65 thousand employees across the globe they are committed to improving safety, efficiency and better diagnosis of diseases. Dedication and passion are the driving forces to face the challenges of developing innovative solutions for global issues and you could be a part of it!

THE ROLE

As a Regulatory Affairs Specialist, you will suppor regulatory activities for new product development, acquiring international registrations, and post-approval maintenance of the international registrations.



ACTIVITIES

- You will support the preparation of global regulatory submissions such as but not limited to clinical trial application, initial registrations, changes/variations, and renewals by:
- Coordination of timely preparation of requests for Free Sale Certificates.
- Work with applicable regulatory agencies and international consulates.
- Coordination and collection of specific registration information with R&D, Manufacturing, QA, and applicable departments, as vital to support registration requirements.
- Collaborate with OEM's to collect registration information.
- Assemble technical information to build a 'clinical report' or a 'dossier'.
- Assist in the preparation of the Technical File for CE marking in accordance with applicable laws and regulations and checklists for other countries such as Australia and Singapore.
- Assemble/assist with 510(k) submission and acquire/support clearance in the U.S.
- Participate in the review and approval of labelling and promotional materials.
- Participate in New Product Development Core Teams and provide regulatory input in these teams including but not limited to the preparation of Regulatory Strategies.
- Maintain departmental procedures (SOP's and work instructions).
- Maintain accurate and complete regulatory files and applicable records.
- Advise in the interpretation and application of IVD regulations as well as the planning and implementation of new and updated regulations.

WHY THIS COMPANY?

This is an opportunity to work in an international company and have professional and personal growth in a challenging and rewarding work environment within dynamic, diverse and international teams.

REQUIREMENTS:

- You have a minimal 3 years of demonstrated ability in regulatory affairs, ideally in the in Vitro diagnostics area or alternatively in the Medical Device industry.
- You have a bachelor's degree in a technical or scientific field in health-care, clinical, engineering, physical, biological, or regulatory sciences, potentially coupled with advanced degrees.
- You have new product development experience, preferably in a global IVD or medical devices company. International registration experience is a plus!
- You have knowledge and understanding of EU and worldwide registration and regulatory requirements.
- You have knowledge of ISO 13485, 21 CFR 820, and new product development (plus)!
- You have strong writing skills (in English and Dutch) and the ability to use appropriate software tools to develop and edit documents for registration purposes.
- You can lead and monitor multiple registrations/projects simultaneously.
- You have strong interpersonal and analytical thinking skills and are able to multitask and meet deadlines.
- You have a high level of integrity, initiative, self-motivation, and energy.
- You have an eye for detail, this is critical

Interested in further conversation?

Please send your CV to monia@elemed.eu to arrange a confidential career discussion.

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