REGULATORY AFFAIRS MANAGER

Posted on 17 maj, 2022

Company Name OnDosis

Location Gothenburg

Job Description

As a Regulatory Affairs Manager, reporting to the COO, you are accountable for the development and execution of regulatory strategies to ensure that business objectives are met and regulatory requirements are fulfilled in the regions where OnDosis products will be marketed.

The role is accountable for planning and execution of regulatory clearance activities for both medical devices as well as our technology being part of drug-device combination products.

Your responsibilities include:

- Represent regulatory affairs in new product development and maintenance projects. Responsible for the creation and maintenance of product related regulatory documentation such as technical documentation according to MDR
- Assess labelling and design changes for impact to existing product registrations
- Accountable for new product registrations and maintenance of current product registrations, including creation and adaptation of technical dossiers in accordance with applicable requirements for the specific market submission in scope
- Accountable for the preparation, filing and maintenance of FDA drug master files (DMF), including selection of and communication with subcontractors for DMF publishing
- Communication with collaboration partners, such as pharmaceutical companies, and subcontractors on regulatory matters, as applicable
- Assume the role as *Person responsible for regulatory compliance (PRRC)* as defined om Article 15 of the EU MDR (2017/745)

Are you the one we are looking for?

We are looking for talented professionals with passion and drive. You have the understanding and experience of working with software/electronics in medical devices. Dealing with many internal and external stakeholders, you have excellent communication skills in English (both written and spoken).

As a Regulatory Affairs Manager, you have:

- In-depth understanding and excellent working knowledge of US FDA requirements, European regulations and guidance from the European Commission and competent authorities and globally applicable regulatory practices on medical devices.
- Experience from specific international standards, such as ISO 14971, IEC 60601, ISO 10993, IEC 62366
- Knowledge of ISO 13485, including full product development and lifecycle requirements for medical devices
- Experience from management, compilation, submission and maintenance of regulatory filings for medical devices, combination products and/or pharmaceuticals

What can OnDosis offer you?

You will have a great opportunity to join early and develop in a global company with really high ambitions. Our clients are large multinational pharmaceutical companies. Your colleagues are all highly skilled professionals with a profound industry knowledge. The commitment to establish a new standard for the dosing of medicines is present in everything we do. For sure, you will be part of an exciting growth journey on the global pharma- and medical devices arena.

Apply today!

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to Ann Rütt to ann.rutt@moveup.se
If you have questions regarding OnDosis or this open position, please contact Ann at +46 (0)733 44 09 00.

By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that we have the right to share this information with third parties (our client). You can revoke the consent whenever you want.

Om företag

***OnDosis** is a Swedish life science company that develops intelligent solutions to deliver individualized medication. By combining first-class pharmaceuticals with digital technology, we create a new, user-friendlier way of taking medicine that optimizes the benefits of prescribed therapies.*

OnDosis will revolutionize the way we take our medicines through integration with intelligent dosing and health technology to improve patient outcomes across a multitude of diseases.

While pharmaceutical innovation has accelerated, dosing has stayed the same, resulting in a great number of unmet needs. Today, the calls for change are at an all-time high—and our revolution will ensure that dosing catches up with the scientific advances of modern medicine and digital therapeutics.

www.ondosis.com

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