QUALITY ASSURANCE MANAGER

Posted on 19 augusti, 2021

Company Name OnDosis

Location Gothenburg

Job Description

As a Quality Assurance Manager, reporting to the COO, you are responsible for the implementation, maintenance and continuous improvement of the OnDosis quality management system, based on ISO 13485, EU Medical Device Regulation, and US Quality System Regulation (CFR Title 21, Part 820). You provide guidance and support quality operations throughout the product lifecycle (from pre- to post-market phase) to ensure product quality and adherence to quality management procedures and regulatory compliance.

Your responsibilities include:

- Lead quality aspects of core projects.
- Maintenance and continuous improvement of the quality management system.
- Manage corrective and preventive actions program, non-conformances, complaint handling, risk management activities, etc., through development, maintenance and adherence to documented processes.
- Promote awareness of quality aspects throughout the organisation and perform/coordinate training in quality management processes.
- Responsible for organising management reviews and compiling/reporting on the performance of the quality management system.
- Plan and manage audit activities.
- Responsible for supplier evaluation, overseeing and directing subcontracted manufacturing, including coordination of external audits.
- Responsible for establishing and maintaining quality agreements with pharma partners and subcontractors.

Are you the one we are looking for?

We are looking for talented professionals with passion and drive. You have a strong attention to details and a quality-oriented mindset. Dealing with many internal and external stakeholders, you have excellent communication skills in English (both written and spoken).

As a Quality Assurance Manager, you have:

- Relevant experience from a quality assurance position in medical devices.
- Demonstrated knowledge of relevant regulations, international standards and guidelines, such as ISO 13485, ISO 14971, MDD, MDR, CFR Part 820, MDSAP.
- Comprehensive experience from developing and delivering effective quality management processes.
- Experience from quality assurance of medical device software (embedded and stand-alone) is an advantage.
- Good working experience from risk management is meriting.
- Experience from regulatory assurance role in medical device or pharmaceutical industry is meriting.
- Experience from drug-device combination products is considered an advantage.

What can OnDosis offer you?

You will have a great opportunity to join early and develop in a company which acts on the global arena 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 Tom Bergqvist at +46 (0)733 87 27 22 or Ann Rütt 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

Consultant Name Ann Rütt

Consultant Number +46 (0) 733 44 09 00

Consultant Email ann.rutt@moveup.se

Cosultant Linkdin https://www.linkedin.com/in/ann-r%C3%BCtt/