TERAPET

Quality Management Systems (QMS) Manager

Terapet SA, a Geneva based CERN MedTech start-up, is developing medical devices based on an innovative technology for imaging in nuclear medicine to bring proton therapy to the next level.

We are looking for a motivated and proactive Quality Management Systems Manager (MDR) to join our small, dynamic, and passionate team.

Role: Quality Systems Manager MDR

Start date – Duration: 01.01.2024 – Permanent (100%)

Place of work: Rue du Pré-Bouvier 7, CH-1242 Satigny

Responsibilities:

We are seeking a Quality Systems Manager to manage the Quality Systems function for a Medical Devices fast-growing business. As the Quality Systems Manager, you will be responsible for ensuring our products comply with all relevant regulatory requirements and standards.

- Set-up and maintain the in-house Quality Management System (QMS) for Medical Devices in compliance with ISO 13485, FDA 21 CFR Part 820, and MDSAP, in collaboration with our external QMS/QA advisor.
- Oversee the implementation and maintenance of policies and procedures related to quality management and control, including document control, change control, risk management, supplier quality, and complaint handling.
- Monitor and evaluate the effectiveness of the QMS through metrics and internal audits.
- Conduct external audits of suppliers and contract manufacturers to ensure compliance with applicable regulatory requirements and quality standards.
- Provide leadership and guidance to the Quality Systems team and cross-functional teams to ensure quality objectives are met and maintained.
- Ensure compliance with all applicable laws, regulations, and industry standards related to Medical Devices.
- Collaborate with Regulatory Affairs, R&D, Manufacturing, and other departments to ensure quality requirements are incorporated into product development, production, and post-market activities.
- Write functional requirement documents and provide guidance on how to write them to the other team members.
- Participate in regulatory inspections and support resolution of any quality-related issues.
- Collaborate with other team members and stakeholders.
- Coordination with external collaborators.

Requirements:

- Bachelor's or master's degree in engineering, life sciences, regulatory affairs or a related field.
- Experience in the medical device field.
- Excellent communication and problem-solving skills. Strong attention to detail and ability to prioritize tasks in fast paced environment.
- Excellent analytical and multitasking skills.
- Good knowledge of English.
- Willingness to work in Geneva.

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Preferred experience:

- Minimum of 2 years of experience in Quality Systems management within Medical Devices, including knowledge of ISO 9001, ISO 13485, FDA 21 CFR Part 820, and MDSAP.
- Experience in conducting internal and external audits and supporting regulatory inspections.
- Notified body experience.
- LEAN or Agile certification.
- Expertise in C++, Java, or other programming languages.

If you want to know more about this job, please contact us on +41 76 339 9580.

This position will be filled as soon as a suitable candidate is found. If you are interested in this job offer, please send your application (including cover letter and CV) to: recruitment@terapet.ch