EBAMed
External Beam Ablation

Sr. Quality Assurance (QA) Manager - Medical device experience required

Workplace: Campus Biotech Innovation Park, Geneva (Switzerland)
Contract type: Permanent contract
Activity rate: 100% - can start at a lower percentage in a transition phase
Eligibility: Swiss work permit / EU nationality
Starting date: not earlier than Sept 1st, 2021

EBAMed develops a medical device to enable non-invasive treatment of cardiac arrhythmias, for the benefit of patients and medical doctors. Our activities focus on real-time ultrasound image processing and optical tracking to monitor and react to cardiac motion. We are looking for a skilled and motivated individual to join our dynamic start-up team. This role requires significant experience supporting products going into FDA/new EU MDR regulated businesses.

Your mission

As a Quality Leader, you will implement and maintains ISO 13485 quality management systems, create and maintain all quality processes/documentation, ensure compliance of personnel to the QMS through coaching and training, fulfill customers' requirements on quality issues and work closely with the management team in fulfilling all of the above.

Responsibilities include:

- Act as primary quality representative for existing and prospective customers
- Oversee and maintain compliance with MDR 2017/745/EU, ISO 13485 and USA 21 CFR part 820
- Review and consolidate product requirements for medical device systems developed at EBAMed according to applicable regulations
- Contribute actively to defining medical device documentation, from user needs and applicable standards, to design verification testing, and give appropriate guidance to the development teams
- Work closely with Clinical Affairs to set up quality files suitable for submission to pre-market clinical investigation as required by Competent Authorities
- Work in collaboration with the Legal team to prepare manufacturing and quality agreements with external providers and suppliers
- Work effectively in close collaboration with external providers or suppliers and perform quality audits
- Create and maintain all quality documentation related to products, including product test protocols, change management and notification processes, corrective and preventative actions (CAPA), customer complaints, audits and related items
- Train and coach EBAMed teams to use, follow and work under QA Processes along the projects
- Oversee the risk management process and oversee its related activities

- Act as the main source of quality and regulatory knowledge and strategy within EBAMed
- Report to management on quality issues, trends and effectiveness.

Profile

- MS in Engineering or relevant Life Science discipline with 5+years of experience in a similar position in the medical device industry (preferably with class III medical devices)
- Detailed understanding of the EU, Swiss and USA medical device regulations, including the MDR 2017/745/EU, the FDA 21 CFR Part 820 and ISO 13485 requirements
- Experience with setting-up and maintenance of Quality Management Systems and Processes for Medical Devices
- Demonstrated skills in risk management (ISO 14971) and documentation compliant with standards and guidelines of the medical device industry (e.g., technical documentation, design history file, Investigational Device Exemption)
- Experience and/or specialization in one or more of the following areas:
    - Active implantable medical devices – ISO 14708 series
    - Medical electrical devices – IEC 60601 series
    - Software as a Medical Device - IEC 62304
    - Medical device usability engineering - IEC 62366
- Experience managing a small team of QA Engineers
- Strong organizational and communication skills, , including ability to communicate with academic scientists and internal clinical teams
- Successfully stay within defined budgets and schedules
- Work independently and within a team
- Possess a positive, “can-do” attitude
- Strong at taking initiative, fast learner
- Attention to details
- Fluency in written and oral English.

We offer

EBAMed offers stimulating work with a passionate team, and the opportunity to grow in an dynamic environment. We offer flexible working hours, and exposure to the most advanced international institutions. If you are eager to take on new challenges, work in a fast-paced collaborative environment and contribute to an innovative start-up with a strong impact in the field of cardiology, you are the perfect fit for our team! More about our activities on EBAMed’s Website and Linked-In

To apply, please send your **CV and cover letter** describing your qualifications, background and interest in this position to **admin-gva@eba-med.com**

Deadline for applications: May 15th, 2021