Is looking for its next:

ISO 13485 Quality Assurance / Regulatory Affairs Manager

Location:

Annecy (France), but remote work is possible

Contract:

Permanent contract – Under French law

Part-time / flexible hours are possible

Start Date: January 1, 2024

Compensation:

To be discussed based on experience. It will be a combination of a fixed salary, bonuses, and stock options.

Mission:

CILIATECH is developing a new implant for glaucoma surgery, not yet commercialized.

You will be responsible for managing and adapting the quality system to meet the various standards required for international commercialization (ISO 13485, MDR 2017/745, MDSAP, FDA 21 CFR 820…), as well as preparing the necessary documentation for registrations outside Europe.

You will also be responsible for product release before market placement.

You will report directly to the R&D and Quality Assurance Manager.

Roles and Responsibilities:

The position encompasses the following tasks:

- Coordinating and implementing the quality assurance policy and suggesting quality improvements.
- Adapting the system to international standards such as MDSAP, FDA 21 CFR 820, etc., in line with commercial deployment.
- Planning, monitoring, and controlling the quality assurance system by validating audit plans, investigating root causes, and addressing major malfunctions.
- Participating in risk management and responding to quality audit inquiries.
- Providing information, advice, and training through quality documentation system oversight, conducting training, and regulatory monitoring.
- Preparing and updating registration files for Europe and foreign countries.
- Certifying and releasing batches, ensuring the compliance of finished products and each batch, monitoring and evaluation.
- The position does not currently involve team management.

Required Skills:

- Ability to develop a comprehensive quality assurance approach tailored to the characteristics and challenges of a small company.
- Proficiency in the regulations applicable to Medical Devices.
- Ability to use quality methods and tools, and define the process evaluation model and technical guidelines.
- Ability to manage quality projects with a proactive approach to continuous improvement.
- Capable of managing and preparing audits.
- Demonstrates precision, responsiveness, and agility.
- A minimum of 3 to 5 years in a similar position is mandatory.
- Strong execution capability, autonomy, with a constructive, entrepreneurial, solution-oriented, and collaborative mindset for project success.
- Proficiency in English is mandatory.

Contact:

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