



Is looking for his:

ISO 13485 Quality Assurance representative

Place:

Annecy (France) but remote work is possible

Contract:

Permanent contract – French law

100% or 80% part time are possible

Starting date: immediate

Remuneration:

To be discussed based on experience. Will be a mix of fixed salary/bonus/stock options

Mission:

1. You will be responsible for managing the quality system in accordance with ISO 13485, MDSAP, European Medical Device Regulation EU 2017/745 and CFR 820
2. You will report directly to the RA-QA manager

Duties:

CILIATECH is a start-up developing a new implant for glaucoma surgery. The CE marking process is underway and requires a comprehensive quality management system.

The position includes the following duties:

1. Follow-up / enforcement of the quality assurance policy and system and periodic evaluation of the effectiveness of the system
2. Planning, monitoring and control of the quality assurance system by validating audit plans, investigating causes and dealing with major deviations
3. Participation in risk management and answering questions about quality audits
4. In charge of regulatory and normative surveillance
5. Information, advice, training through the supervision of the quality documentation system, training and regulatory monitoring
6. Update and preparation of files for EU and foreign country approval
7. The position does not include team management at this stage

Skills:

1. Know-how to manage and improve a quality assurance system, adapted to the characteristics and challenges of a small company
2. Mastering the regulations applicable to Medical Devices and ISO13485
3. Know how to use quality methods and tools
4. Know how to manage quality projects in a proactive continuous improvement approach
5. Be able to manage and prepare audits
6. Be rigorous, responsive and agile
7. A minimum of 3 years in a similar position is mandatory
8. You have a strong ability to execute, are autonomous with a constructive, entrepreneurial, solution-oriented and collaborative spirit for the success of the project
9. Fluency in English is mandatory (minimum level C1)

Contact us:

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