Is looking for:

Clinical Affairs manager

Place:

Annecy (France) but work from remote is possible

Contract:

Permanent contract – French law

Part time / flexible time / consulting are possible

Package:

To be discussed according to experience. Will be a mix of fix wage / bonus / stock options

Mission:

- You will be in charge to establish the long-term clinical strategy to support regulatory and marketing needs, and then to organise and coordinate the roll-out of all clinical trials from scratch until final report
- You will be the 2nd employee of the Company, reporting directly to the CEO, and in close connection with the Medical Director

Duties:

CILIATECH is a 5 years old start-up developing a novel implant for glaucoma surgery. Some clinical trials were already launched, some others to support CE marking, and later on FDA approval, shall be organised.

The job encompasses the following expertise:

Clinical Affairs:

- Ensure recovery and follow-up of the already-running clinical trials: coordination with PI, CRO, scientific committee, data safety monitoring board. Responsible for vigilance. Coordinates data base freeze, statistical analysis up to publication preparation. In charge of DSMB agenda, presentation and reports writing, as well as annual reports
- According to the clinical strategy: implement each new trial in European and foreign countries according to applicable guidelines with the support of CROs. Select most appropriate investigation sites, decide on the most effective trial organisation, manage protocols, IBs and data collection, select and manage investigators and CROs
- Establish the safety monitoring plan and the clinical trial risk analysis reports, propose and implement operational tools for clinical trials management (eTMF, eCRF, …)
- Once the strategy for FDA approval will be defined, monitor the trial in USA according to applicable guidelines with the support of CROs.
- Vigilance: organise the reporting information chain to competent authorities, prepare necessary reporting in timely manner whenever necessary

Necessary skills:

- Shall show some solid experience in Clinical Affairs, at field and management level
- Knows ISO 14155, ISO 13485, MDR, and 21CFR
- A minimum of 3 to 5 years of experience is mandatory
- Ideally worked in ophthalmology / glaucoma
- The candidate shall show good selection and coordination skills with 3rd parties. However, the company being small, and the budget being used wisely, some duties will have to be implemented by the candidate himself
- You have a strong capacity for execution, are autonomous with a builder's spirit, entrepreneurial, solution-oriented and collaborative for the success of the project
- English fluency mandatory

Contact us:

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