

Clinical Affairs Manager

HeartKinetics is a Medtech company dedicated to the remote screening and monitoring of patients with heart failure. Created in 2019, HeartKinetics began in the space field thanks to technology for monitoring the heart function of astronauts during their stay in space. Building on the results obtained as part of this ESA-funded project, HeartKinetics now aims to revolutionize the management of heart failure, the leading cause of death worldwide with nearly 65 million cases recorded.

The Clinical Affairs Manager, shall provide support for the development of innovative medical devices, as part of the R&D team. This position is primarily responsible for the review and preparation of documentation packages for notified bodies, FDA, and competent authorities.

About the role

- Preparation of CEP and CER
- Support for management of clinical investigation
- Set up and follow up PMS, PMCF, PSUR
- Review and preparation of documentation packages for FDA submissions, and competent authorities.
- Communicates and collaborates w/ study team including internal and external parties, sponsors, and PI

Your Profile

- Minimum 3 years of relevant experience in Medical Devices QA/RA functions.
- Good understanding of medical devices environment
- Good knowledge of medical devices clinical investigation clearance process (EU and US)
- Good knowledge of medical devices risk management, CIP, CIR, CEP, CER, PMS, PMCF, PSUR
- Very good command of English and French or Dutch.
- At least one application or experience with the FDA for a medical device, preferably software medical device.
- Detail oriented and meticulous in all aspects of work
- Strong follow through skills and ability to proactively identify and solve problems; demonstrated initiative is imperative.
- Ability to work well independently as well as in team environment.
- Experience with EU, Middle east or other competent authorities is a plus.
- Experience in tele-medicine medical device is a plus.

We offer you

- A permanent position with a competitive package in a fast-growing start-up in a booming sector
A full-time position
- A stimulating working environment within a team of enthusiastic entrepreneurs
- Working on a technology that will revolutionize healthcare and will positively impact society.

Contact

Send your CV and a motivation letter to the attention of R&D Manager Amin Hossein, by e-mail at amin@heartkinetics.com