About Perfuze

Perfuze are developing innovative catheter-based technology to remove clots from the brain following Acute Ischemic Stroke. The technology is designed to provide superior clinical outcomes in shorter procedural times, resulting in safe, cost-effective therapy. Perfuze is based in Dangan on the west side of Galway City.

Clinical Affairs Specialist

The primary responsibility of the Clinical Affairs Specialist is to assist with the design, planning and execution of clinical trials for Perfuze products. The Clinical Affairs Specialist will also prepare and submit applications for clinical investigations. The position requires a high level of innovative thought and problem-solving skills. In order to coordinate the variety of regulatory related tasks, the role requires a high degree of flexibility, and structured time and task management.

Responsibilities

- Prepare clinical documents for submission to Ethics Committees, Institutional Review Boards and regulatory authorities such as the FDA and Competent Authorities.
- Liaise with external vendors such as CROs, core labs, medical monitors, biostatisticians, and data management vendors.
- Liaise with study coordinators and investigational site personnel to coordinate clinical trial activities.
- Assist with tracking patient enrolment and data management.
- Ensure clinical data is correctly documented and analysed.
- Coordinate review and reporting of safety events from clinical investigations.
- Assist with compiling clinical investigation and clinical evaluation reports.
- Provide clinical input to post-market surveillance activities.
- Adhere to Perfuze SOPs, Good Clinical Practice regulations, and other relevant regulatory requirements.

Requirements

- Degree in Engineering or Science discipline
- Minimum of 2 years' experience in the medical device or pharmaceutical industry, or a PhD in a life science discipline
- Understanding of clinical trial requirements and Good Clinical Practice.
- Strong technical aptitude with an ability to analyse and challenge data, identify and address gaps, and generate clinical reports to support submissions
- Self-motivated and clear minded approach to leading support of clinical activities
- Good interpersonal & communication skills essential
- Excellent writing skills and comprehension skills
- Experience working in an SME environment desirable, preferably in a medtech start-up
- Commit to ongoing personal development to improve technical and non-technical skillsets
- Experience in preparation of clinical trial documentation desirable
- A hands-on mindset

If interested, please submit your CV and a letter outlining why you are the right person for the role via Indeed at ie.indeed.com/jobs?q=perfuze&l=Galway.