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.

Director of Clinical Affairs

The primary responsibility of the Director of Clinical Affairs is to define, lead and execute the vision and clinical strategy that will support Perfuze business objectives. The Director of Clinical Affairs is responsible for the design, planning and successful execution of clinical trials that demonstrate the safety and effectiveness of Perfuze products. This leadership role requires a high level of innovative thought and strategic planning capability.

Responsibilities

- Translate company objectives into clinical trial design and publication strategy.
- Lead discussions with regulatory authorities to ensure trial design addresses regulatory requirements.
- Develop and maintain collaborations with clinical investigators and key opinion leaders to ensure clinical development programs have optimal design and are aligned with state-of-the-art.
- Develop clinical protocols, timelines, and budgets.
- Obtain necessary clinical trial approvals from IRBs, Ethics Committees, and regulatory authorities such as the FDA and Competent Authorities.
- Manage and develop Perfuze clinical affairs team.
- Manage external vendors such as CROs, core labs, medical monitors, biostatisticians, and data management vendors.
- Lead the process for selection and contracting of sites and investigators.
- Track patient enrolment and take corrective actions to address recruitment issues.
- Ensure clinical investigation reports are documented clearly for regulatory submissions.
- Provide clinical input to clinical evaluations and 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 10 years' experience in the pharmaceutical or medical device industry including 7 years managing clinical affairs in medical devices
- Solid track record in managing clinical trials
- Requires strong technical and client management skills, the ability to work with cross-functional teams: Commercial, Engineering, Regulatory Affairs, and Marketing.
- Self-motivated and clear minded approach to clinical activities
- Good interpersonal & communication skills essential
- Excellent writing and comprehension skills
- Commitment to ongoing personal development to improve technical and non-technical skillsets
- Experience working in an SME environment desirable, preferably in a medtech start-up
- 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. If you wish to learn more about the role email info@perfuze.com for the attention of the Wayne Allen, CEO at Perfuze.