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.

Regulatory Specialist

The primary responsibility of the Regulatory Specialist is to prepare and submit regulatory filings for Perfuze products, as well as ensuring products and procedures comply with regulatory requirements. Supports necessary regulatory activities required for product market entry and maintenance. 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

- Contribute to development of US and EU regulatory strategies for product submissions through identification of relevant test requirements.
- Prepare regulatory filings to FDA, including 510(k) premarket notifications, IDE applications, IDE supplements, Annual Progress Reports, and subsequent FDA correspondence.
- Prepare and coordinate CE mark submissions/change notifications and Notified Body interactions.
- Maintain Technical Documentation according to the requirements of the Medical Device Directive/ Medical Device Regulation.
- Provide regulatory input to clinical investigations/clinical evaluations.
- Provide input to the Change Control process for design, manufacturing, and specification changes to assess impact on regulatory compliance and requirements.
- Represent Regulatory Affairs within project teams to provide regulatory strategy and direction.
- Provide regulatory input to customer complaints.
- Coordinate post-market surveillance and vigilance activities.
- Develop and maintain regulatory procedures.

Requirements

- Degree in Engineering or Science discipline
- Minimum of 2 years' experience in the medical device industry or pharmaceutical industry, or a PhD in a life science discipline
- Understanding of FDA, ISO, MDD and MDR requirements, with the ability to interpret and implement these requirements
- Strong technical aptitude with an ability to analyse and challenge data, identify and address gaps, and generate technical reports to support submissions
- Self-motivated and clear minded approach to regulatory activities
- Good interpersonal & communication skills essential
- Excellent writing and comprehension skills
- Experience working in an SME environment, preferably in a medtech start-up
- Commitment to ongoing personal development to improve technical and non-technical skillsets
- Experience in preparation of regulatory submissions 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.

Perfuze Ltd., IDA Business Park, Dangan, Galway