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.

Senior Regulatory Specialist

The primary responsibility of the Senior Regulatory Specialist is to oversee regulatory filings for Perfuze products, as well as ensuring products and procedures comply with regulatory requirements. Coordinates 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 US and EU regulatory strategies for product submissions through identification of relevant test requirements.
- Compile and coordinate regulatory filings to FDA, including 510(k) premarket notifications, IDE applications, IDE supplements, Annual Progress Reports, and subsequent FDA correspondence.
- Coordinate CE mark submissions/change notifications and Notified Body interactions.
- Prepare and coordinate updates to Technical Documentation according to MDD/MDR.
- Provide regulatory input into clinical investigations/evaluations.
- Identify updated regulatory requirements and standards, and perform gap analyses to assess changes.
- Provide input to the Change Control process for design, manufacturing, and specification changes.
- Represent Regulatory Affairs within project teams to provide regulatory strategy and direction.
- Provide regulatory input in response to customer complaints.
- Coordinate post-market surveillance and vigilance processes.
- Develop and maintain regulatory procedures.
- Review advertising and promotional material.
- Participate in design control activities as required.

Requirements

- Degree in Engineering or Science discipline
- Minimum of 4 years' experience in the medical device industry
- Experience in preparation of regulatory submissions
- Understanding of and ability to interpret and implement FDA, ISO, MDD and MDR 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
- A hands-on mindset

If interested, please submit your CV and a letter outlining why you are the right person for the role to hr@perfuze.com