Regulatory Specialist

About Perfuze

Perfuze is a growth stage medical device company, based in Galway, dedicated to improving the quality of life for stroke patients. Perfuze is developing innovative catheter-based technology to extract blood clots from the brain following an Acute Ischemic Stroke. We are located in the IDA Business Park in Dangan, Galway. Millipede technology has been recognised by the FDA through the granting of a Breakthrough Device Designation and was awarded CE Mark in 2021. At Perfuze, we push the limits of what medical technology can do to help restore health and extend life. Our mission is to halve the number of patients who suffer disability post stroke treatment. We want to accelerate and advance our ability to create significant innovations, but we will only succeed with the right people on our team.

Our Culture

- An inclusive work environment, where all the employees are valued, supported, and encouraged
- All employees have a seat at the table and have influence
- A collaborative teamwork environment where learning is constant, and performance is rewarded
- The opportunity to be at the forefront of a technology that can positively impact the treatment of one of the world's most devastating diseases

Regulatory Specialist Role

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. Although this role is based at our Dangan facility some hybrid working may be supported in accordance with company policy.

How You'll Contribute

- 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.

Must Have

- Degree in Engineering or Science discipline
- Minimum of 2 years' experience in the medical device industry
- 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 note outlining why you're the right person for the role on indeed.ie at https://ie.indeed.com/jobs?q=perfuze&l=