## 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 & Clinical Affairs Specialist

The primary responsibility of the Regulatory & Clinical Affairs Specialist is to prepare and submit regulatory filings and applications for clinical investigations of 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

- Assist with preparation of 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 Files, Essential Requirements Checklists, Risk Management Files and Design History Files.
- Provide input to the Change Control process for SOPs, Test Methods, Process Changes, Design Changes and Labelling to assess impact on regulatory compliance and requirements.
- Represent Regulatory Affairs within project teams to ensure all regulatory requirements are met throughout the development process.
- Coordinate post-market surveillance and vigilance activities.
- Prepare clinical documents for submission to Ethics Committees and Institutional Review Boards.
- Coordinate review and reporting of safety events from clinical investigations.
- Assist with compiling clinical investigation reports.

### Requirements

- 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 these requirements and implement them into a lean, compliant QMS
- 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 leading support of regulatory and clinical activities
- Good interpersonal & communication skills essential
- Excellent writing skills and comprehension skills
- Experience working in an SME environment, preferably in a medtech start-up
- Commit 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 to info@perfuze.com