



About Perfuzé

Perfuzé 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. Perfuzé is based in Dangan on the west side of Galway City.

Design Assurance Engineer

The primary responsibility of the Design Assurance Engineer is to work closely with the R&D team to implement design control activities for new products and design changes to existing products. Provides guidance to project teams in the areas of design control and risk management. The position requires a high level of innovative thought and problem-solving skills. In order to coordinate activities across multiple projects, the role requires a high degree of flexibility, and structured time and task management.

Responsibilities

- Develop design verification and design validation protocols and reports.
- Define requirements for design reviews and ensure they are conducted according to applicable requirements.
- Generate usability plans, protocols, and reports.
- Support development of design inputs based on risk management outputs.
- Oversee risk management activities throughout development projects.
- Perform technical reviews of design documentation, test data and reports.
- Support development of new test methods and test method validation.
- Provide input to the Change Control process for design, manufacturing, and specification changes.
- Represent Design Assurance within project teams to provide design assurance and risk management guidance and direction.
- Support design transfer activities, including process validation activities.
- Provide design assurance input to non-conformance reports and complaints.
- Participate in Corrective and Preventive Actions.
- Support audits and provides design assurance input into audit findings as required.
- Support regulatory filings.

Requirements

- Degree in Engineering or Science discipline
- Minimum of 2 years' experience in the medical device industry
- Experience in design control and product development
- Strong technical aptitude with an ability to analyse and challenge data, identify and address gaps, and generate technical reports
- Self-motivated and clear minded approach to design control 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@perfuzé.com