



About Perfuze

Perfuzer are developing innovative catheter-based technology to treat acute ischemic stroke. The technology will provide superior clinical outcomes in shorter procedural times; resulting in safe, cost-effective therapy. Perfuzer is based in Galway City. It is anticipated that the position will commence in July 2019.

Senior Quality Engineer

In this role you will be supporting the Perfuzer technology from concept to clinical study and commercialisation.

Responsibilities

- Development, implementation and maintenance of a robust and fully compliant quality system in accordance with ISO 13485
- Procedure draft and refinement
- Management of change and design control
- Ensure product quality standards are met both internally and at external manufacturing facility
- Support and management of sub-contract suppliers in device manufacture
- Internal and external auditing
- Development and implementation of risk management procedures
- Support of product development activities including test programs and product builds

Requirements

- Degree in Engineering or Science discipline
- Minimum of 6 years' experience in the medical device industry, with experience in manufacturing, quality, or design assurance roles
- The successful candidate will have a relevant proven track record and complete commitment to achieving goals
- Deep and current understanding of FDA and ISO 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 manufacturing line setup and design assurance activities
- Good interpersonal & communication skills essential
- Experience working with sub-contract manufacturers/suppliers, including integration of quality management systems, essential.
- Excellent writing skills and comprehension skills
- Experience working in an SME environment
- Commit to ongoing personal development to improve technical and non-technical skillsets
- Experience in preparation of regulatory submissions desirable
- Experience working in a medtech start-up preferable
- A hands-on mindset

If interested, please submit your CV and a letter outlining why you're the right person for the role to info@perfuzer.com for the attention of Liam Mullins.