



Senior Quality Engineer

About Perfuzze

Perfuzze is a growth stage medical device company, based in Galway, dedicated to improving the quality of life for stroke patients. Perfuzze is developing innovative catheter-based technology to extract blood clots from the brain following an Acute Ischemic Stroke. At Perfuzze, 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. Perfuzze is based in Dangan on the west side of Galway City.

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.

Senior Quality Engineer role

As a Senior Quality Engineer, you will provide support in quality systems, supplier quality and manufacturing activities with a focus on continuous improvement of products and processes. You will support the execution of initiatives and projects to enhance quality performance within the business, ensuring compliance to regulations and standards.

How You'll Contribute

- Support the maintenance of a quality management system that complies with the Medical Device Regulation (MDR) EU 2017/745, the FDA Quality Management System Regulation 21 CFR 820 and ISO 13485.
- Lead quality activities related to outsourced manufacturers and suppliers to ensure compliance is maintained for Perfuzze products.
- Lead risk management activities including hazard/failure mode effects analysis.
- Drive risk-based problem solving to assure product quality and patient safety through both design activities and manufacturing processes.
- Work closely with cross functional engineering colleagues to lead product transfer quality deliverables.
- Lead process verification and validation activities in accordance with quality system policies and practices.
- Own and manage internal and supplier driven non-conformances (NCs) and CAPAs, ensuring timely containment actions, corrections, root cause investigation, implementation of corrective actions, and closure.
- Support in-house manufacturing to ensure high quality products are delivered.
- Apply a risk based approach to solve problems related to product quality.
- Monitor KPIs for process and/or product quality, perform analysis and interpret trends.

Must Have:

- Degree in Engineering or Science discipline.
- 5+ years' quality or manufacturing experience in the medical device industry
- Thorough knowledge of Good Manufacturing Practice as described in US and European regulations for medical device manufacture.
- Excellent knowledge of the application of ISO 14971; Risk Management, throughout the QMS.
- Demonstrated ability to make challenging decisions to support continued supply of products, while also maintaining compliance.
- Strong self-management and organisational skills, ability to manage workload, ability to set and adjust priorities to align with company goals.
- Ability to interface with and effectively communicate with a broad range of stakeholders and cross functional teams, as well as executive management.
- Experienced in identifying and executing continuous improvement initiatives.
- 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