



## Quality Manager

### 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 remove clots from the brain following 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.

### Quality Manager

As Quality Manager you will be responsible for all Quality processes at Perfuzze. The position requires a high level of oversight and understanding of the impact of quality processes on business needs.

### How You'll Contribute

- Act as Management Representative as outlined in ISO 13485:2016 5.5.2.
- Act as Local Actor Administrator (LAA) for EUDAMED database on behalf of Perfuzze.
- Report to top management on the effectiveness of the quality management system and any need for improvement.
- Manage and maintain the quality management system in compliance with the Medical Device Directive (MDD), Medical Device Regulation (MDR) EU 2017/745, the FDA Quality Management System Regulation 21 CFR 820 and ISO 13485.
- Promote awareness of applicable regulatory requirements and quality management system requirements throughout the organization.
- Identify and manage resources required for effective functioning of QA activities.
- Manage Perfuzze's internal and external audit programs as well as acting as host for Notified Body and FDA inspection audits.
- Manage the Corrective and Preventive Action process
- Manage Risk Management activities, ensuring appropriate risk evaluations are documented to support change control activities.
- Manage supplier quality activities, including supplier onboarding, execution of supplier quality agreements, routine supplier evaluations and onsite audits etc.
- Manage and support quality operation activities at contract manufacturing sites.
- Responsible for quality management aspects of Perfuzze's cleanroom operation, validation and monitoring.
- Support process validations and equipment control process.
- Manage the quality aspects of receiving inspection and non-conforming material processes.
- Drive continuous improvement of the QMS to meet expectations of customers, business partners and regulations.

- Support device development projects as required to ensure that the appropriate quality requirements are applied.
- Supports Regulatory Affairs for Regulatory Filing and Technical file documentations

### Must Have

- Degree in Engineering, Science or health-related discipline.
- 7+ years' experience in quality assurance in the medical device industry.
- Experienced in the support of outsourced manufacturers and suppliers to identify and mitigate supply chain risks related to quality assurance.
- Excellent 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.
- Skilled in Class 8 cleanroom compliance.
- 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 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](mailto:info@perfuze.com)