Who are we?

SymPhysis Medical are an early-stage start-up focused on developing patient solutions in the area of palliative care. Our initial technology platform is a smart catheter-based device used to treat the build-up of fluid in the body as a result of late-stage cancers.

Over the past 5 years the founders, who are passionate about developing patient-centred products, have built strong and lasting relationships with partners that have helped fast-track the development of their disruptive releaze device. As a result of this success and momentum, SymPhysis Medical is hiring a Senior QA/DA Engineer to join the team based in Galway.

The opportunity

As Senior Quality/Design Assurance Engineer you will get the opportunity to apply your engineering knowledge in areas such as quality systems, supplier controls, design assurance, test method development and validation, design controls, and regulatory affairs during this exciting time at Symphysis as we bring our products to market. We are a high paced start-up moving from Phase 2 to Phase 4 within the next 18 months working closely with our Contact Manufacturer.

What experience do you need?

- Minimum Bachelor's degree in science, engineering, or related field
- Minimum of five (5) years in a similar role in medical device quality systems (preferably experience as a Quality Systems or Supplier Quality Engineer).
- Experience working in both an FDA and European regulatory environment is a pre-requisite.
- Experience with medical device regulations including GMP (Good Manufacturing Practices), QSR (Quality Systems Regulations), and ISO quality requirements, is required.
- Experience working under medical device design controls, with proven knowledge of design verification/validation and design/process FMEAs.
- Strong initiative and follow through in executing responsibilities, overcoming obstacles and balancing multiple priorities effectively through strong technical and/or project leadership experience is required.
- Excellent problem-solving, decision-making, and root cause analysis skills are desired (DMAIC).
- Knowledge and demonstrated practice of risk management methodologies as per ISO 14971.
- Experience in Ethylene Oxide sterilization, biocompatibility, and transportation testing is an advantage.
- Proficiency with MS Office suite is required
- Desired experience in class II and above medical devices.

SymPhysis™ MEDICAL

Our vision & goal

Our vision is to 'Make Every Day Count' for people requiring palliative care and to build a scalable Irish business focusing on providing unrivalled patient independence. With our core clinical ties in Ireland, we are also working with some of the top cancer centres in the US. Our global ambition is to expand into multiple therapeutic areas where we can apply our technology to improve patients' quality of life, reduce hospital costs and help enable patient independence.

By working closely with our clinical, academic and manufacturing partners in the coming years we will be completing design freeze, pre-clinical and clinical trials, human factors studies, DV&V and FDA regulatory submission with the target of launching in the US market in 2023 following with Europe shortly after.

Competitive salary, stock options, flexible working hours, based in a new, state of the art innovation hub.

If you're ready to accelerate your career by joining a start-up who's at the forefront of innovation & research in the respiratory area specialising in palliative care we'd love to hear from you.

Email your CV with cover letter to: info@symphysismedical.com