Company Background

Signum Surgical is a well-funded, early stage start up based in the Galway Docks area. We are developing a solution for perianal fistula – a painful colorectal condition affecting many patients worldwide. We are incredibly passionate about our company and our patients and are looking for someone who feels the same. The company is preparing for first-in-man clinical trials.

Position

We are recruiting a Design Assurance Engineer who has experience working in the medical device industry and recognises the need to be flexible and creative while meeting the standards of medical device regulation. The position will involve working with a small team that is driven to provide successful patient outcomes under tight time constraints. Substantial contribution to FDA regulatory filings and experience of bioabsorbable materials or delivery systems is advantageous. We need someone who can work independently, identify product risks and mitigations, and ensure relevant standards are complied with. The person will act as independent reviewer for all design activities including design changes.

As an early stage start up, hours are demanding but flexible. We are located on the Galway Docks but have an international presence, so we need someone who is able to travel - sometimes on short notice.

Skills

Working in a small team, the successful candidate will need to be flexible and adaptable with an excellent ability to work both cross functionally and independently. The position will require someone who is driven to contributing to team success by taking ownership for tasks. Excellent trouble-shooting, analytical and problem solving skills combined with strong planning and project management skills will be required. The ability to lead, direct and coach others is a must.

The position will require familiarity with a majority of the following: verification and validation protocol development, testing and report generation, sterilization techniques and their validation, packaging requirements and testing methods, design for manufacturing and design controls under quality management systems. Excellent written and presentation skills are a necessity.

Qualifications / Experience

A minimum of a Bachelor's Degree in Mechanical Engineering or Bioengineering combined with 5+ years direct work experience in the medical device industry. Formal training in product risk management, problem solving methods, reliability engineering, process validation, usability or biocompatibility would be advantageous.

Contact

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