Senior Design Assurance Engineer/ Design Assurance Engineer
Full-time, Galway Office

Summary
Working as part of the development teams in the development of Veryan's new stent platforms. Working predominantly on projects to introduce or improve products for treatment of a range of peripheral arterial disease states. Design Assurance is integrated with the Product Development process. The Design Assurance Engineer will support the Company's product development and commercialisation strategy.

Job description and person specification

Principal Responsibilities

- Provide Design Assurance input to R&D project teams for designated projects.
- Understanding the Regulatory requirements for device developments and providing input to projects to encompass these requirements.
- Participate in the generation of Design Input / Output documents.
- Participate in specification development in relation to design input development.
- Drive the risk management activities for designated projects and design changes.
- Design, development and validation of test methods as required to support development programs.
- Develop and maintain design verification and validation plans, protocols and reports.
- Support R&D in the preparation and delivery of Design Reviews and associated checklists.
- Support the conduct of non-clinical studies at third party facilities in conjunction with R&D department.
- Establish and maintain the Design History File and associated documents.
- Provide QA support to R&D for equipment management
- Execute assigned aspects of the project, as required.
- Work within the quality system and ensuring that the quality policy and company systems and procedures are complied with in line with the Medical Device Directive 93/42/EEC, Medical Device Directive 2007/47/EC, MDR 2017/745, FDA Quality System Regulations 21 CFR Part 820, FDA GLP Regulation 21 CFR 58, ISO 13485, ISO 14971, Japanese Ministerial Ordinance # 169.
- Support the development / evolution of the Veryan Design Control, Risk Management and associated systems, to encompass new product development technologies.

Education & Training
A degree level qualification in Engineering, Science, QA or related field is required.

Experience

- A minimum of five/three years' relevant experience in the medical device or pharmaceutical industry, preferably with Stent and Stent Coating technology experience.
- An understanding of ISO 13485, ISO 14971 and FDA QSRs is a prerequisite.
- Familiarity with statistics, validation and physical testing is required.
- Good communication and organizational skills, and the ability to present reports neatly and accurately is essential.
- Experience in DES is an advantage

To apply for this role, please send your CV and a covering email to Jo Graver, HR Manager, email jo.graver@veryanmed.com, quoting vacancy ref