Senior Design Assurance Engineer (Sustaining)
Full-time, Galway Office – Veryan Innovation Centre
Ref: V138

Summary

Veryan people are the best at what we do. We share a commitment, a passion and a vision for the contribution Veryan makes to innovation in interventional medicine.

Veryan people power Veryan's business. Whether they are design engineers, quality engineers, clinical study managers or sales specialists, our people bring an unmatched expertise in each of their fields that both inspires and challenges.

Veryan's culture of innovation helps each individual develop both professionally and personally, and our culture of respect means that we all work in a collaborative, supportive and exciting environment.

Reporting to the Senior Design Assurance Manager, the successful candidate will work predominantly as part of the sustaining team. On occasion the Sustaining Design Assurance Engineer will support new development projects to introduce or improve products for treatment of a range of diseases. This role will involve extensive collaboration with Operations, Quality Assurance, R&D and Regulatory Affairs to support Veryan's commercialisation strategy.

The Design Assurance role can be shaped depending on the experience of the successful candidate, to include the level of the role and the area of expertise (e.g. Human Factors, Usability Engineering, Risk Management, Biological Evaluation, Sterilisation, non-clinical / bench testing, test methods, laboratory testing, etc.). As Veryan is a growing organisation, with a number of R&D projects underway, we want to give our people the opportunity to grow and develop and move within the organisation to suit their needs. We do not hold people back; we inspire and empower.

Primary Job requirements

Principal Responsibilities

- Work within the quality system to ensure 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, Medical Device Regulation 2017/745, FDA Quality System Regulations 21 CFR § 820, FDA GLP Regulation 21 CFR § 58, FDA Labelling Regulation 21 CFR § 801, ISO 13485, ISO 14971 and Japanese Ministerial Ordinance # 169.
- Support the development / evolution of the Veryan Design Control, Risk Management and associated systems, to encompass sustaining activities.
- Provide Design Assurance input to commercial activities:

- Understand the regulatory requirements for device development, specifically design control under device change and provide input to encompass these requirements.
- Lead the design verification and design validation assessment of design changes.
- Manage the system for Design History File creation and maintenance for new and commercialised devices ensuring regulatory and procedural requirements are met.
- Lead the risk management activities for designated sustaining projects, design changes, complaints and CAPAs including quarterly and annual risk management reviews in line with ISO 14971 and Veryan procedures.
- Develop and maintain design verification and validation plans, protocols, and reports for design changes.
- Support the project DA engineer(s) in the preparation and delivery of Design Transfer to Commercial Reviews and associated checklists.
- Support the execution of non-clinical studies at third party facilities, in conjunction with R&D department.
- Provide DA support to R&D for equipment management and validation.
- Manage the labelling and packaging requirements of new and commercial products identifying upcoming changes to labelling and co-ordinate with R&D for timely implementation.
- Co-ordinate the annual risk management review for commercialised devices
- Execute gap analysis to standards, ASTMs and other associated documents.

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

Experience
- Upwards of 5 years' relevant experience in the medical device industry, preferably with class IIb or III device design assurance 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, organizational skills, and the ability to present reports neatly and accurately is essential.