Principal Regulatory Affairs Lead
Full-time, Galway Office – Veryan Innovation Centre
Ref: V151

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.

Due to continued expansion of our product development portfolio and innovation mandate, we are looking to add an experienced Principal Regulatory Affairs Lead to help drive our regulatory strategy and engage directly with key regulatory bodies across the globe in support of these projects.

This is a highly collaborative position working closely with all functions at all levels to plan, lead and manage the successful achievement of the Regulatory Affair's project deliverables across the product development process. You will report to the Director of Regulatory Affairs in our new Innovation Centre in Galway.

Job requirements

Principal Responsibilities

- Lead compilation of international regulatory submissions for Veryan products under development.
- Manage regulatory submission timelines, identify risks and appropriate mitigations.
- Review the data intended for submission in international regulatory applications. Identify gaps and make recommendations.
- Participate in risk management activities for designated projects.
- Provide regulatory input during design control process to Veryan development projects.
- Support CE Mark maintenance and substantial change submissions to notified body.
- Define and capture the regulatory strategy for the development project(s).
- Co-ordinate and support regulatory reviews and meetings with EU Notified Bodies, Competent Authorities, FDA, PMDA and NMPA.

- Review and contribute to regulatory aspects of change control, non-conforming process, labelling changes etc.
- Support routine safety reporting activities for clinical investigations.
- Support vigilance reporting activities in Veryan.
- Support post market surveillance reporting, annual progress reports.
- Review and contribute to clinical evaluation reporting activities.
- Work within the quality system and 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, MDR 2017/745, FDA Quality System Regulations 21 CFR Part 820 ,ISO 14971, and Japanese Ministerial Ordinance #169.
- Work towards achieving compliance to the Medical Device Regulation 2017/745.

Education & Training

- Degree level qualification in engineering or a strongly related field.

Experience

- A minimum of 5 years' relevant regulatory experience in a senior regulatory role in the medical device or pharmaceutical industry, ideally with Class IIb and Class III medical devices.
- Technical competency of ISO13485:2016, MDD 93/42/EEC, MDR 2017/745, and the FDA QSRs is a prerequisite.
- Good communication and organizational skills, computer literacy and the ability to present reports neatly and accurately is essential.