Regulatory Affairs Director
Full-time, Galway Office – Veryan Innovation Centre
Ref: V196

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 Head of Global Clinical & Regulatory Affairs, the position of Regulatory Affairs Director is responsible for registration in highly regulated markets of the newly developed products and the existing portfolio and will manage the Regulatory Affairs function which includes a pre-market and post-market team.

Primary Job requirements

Principal Responsibilities

- Provide leadership and management direction to the regulatory affairs team
- Responsible for driving the global regulatory strategy aligned with business objectives
- Ensure timely execution of regulatory strategies to support launch activities and compliance status for maintenance projects and activities
- Serve as a principal interface with global regulators to facilitate review and approval of submissions
- Establish strong partnerships with internal and external stakeholders
- Provide regulatory guidance, strategic and tactical advice to project teams, including identifying and assessing regulatory risks, managing issues and finding solutions for complex problems
- Provide interpretation of regulatory guidance documents, regulations and directives regarding their applicability and impact on internal programs
- Ensure companies compliance to the relevant provisions of the Medical Device Directive 93/42/EEC, Medical Device Directive 2007/47/EC, MDR 2017/745, FDA and PMDA requirements and any other national or local requirements
- Provide an interface to the company's clinical group to ensure all clinical operations are conducted in compliance with the relevant regulatory requirements in the jurisdictions where clinical studies are implemented

- Ensure all commercial activities undertaken by the Company or its distributors are conducted in full compliance with relevant legislation and regulation, including the promotional content and advertising across all media
- Develop training plans and programs to enhance regulatory operations

Education & Training
University degree in natural science, pharmacy, pharmacology, medicine or engineering

Experience
- 7 years minimum experience in regulatory affairs in the medical device or pharmaceutical industry.
- Competence in the regulatory requirements of the MDD, MDR and FDA Regulations is a prerequisite.
- Good communication, organizational skills, and the ability to present reports neatly and accurately is essential.
- Independent, reliable and communicative personality who can deliver high-quality work even under pressure and handle several projects simultaneously