Regulatory Affairs Manager

Reach your career goals with Eirgen Pharma, your future could be here

Would you like to be part of a company that has the courage, innovation, and capability to improve and enhance patient lives across the globe?

Eirgen was founded in 2005 and since then we have continually grown and now employ over 180 employees at our site in Waterford. Our strengths lie in our capability to rapidly introduce new products and add additional volume to existing products - ensuring supply for new product launches and expanding market opportunities.

What makes us different is that while we continue to grow our business we have still maintained that small company feel to our culture which enables us to ensure that our employees are always front and centre in everything we do. By creating a progressive and dynamic working environment, where hard work and enjoyment aren't mutually exclusive, we have created a high performing, people-centric culture which allows us to work in an environment where the focus is always on ensuring that the patient comes first.

About the Job

You are responsible for supporting the development and successful performance of the regulatory strategy for Eirgen's pipeline of Oral Solid Dose products.

Your areas of responsibility will include:

- Interpret global regulations and guidance to identify risks and provide input for guidance to cross functional product teams.
- Partner with cross-functional stakeholders both internally and externally to deliver regulatory dossiers (e.g. CMC component(s) of IND / IMPD / Master Files, amendments, annual reports) and health authority interaction briefing documents.
- Manage and maintain regulatory dossiers as required throughout the product development lifecycle.
- Review, compile and ensure that submission documents and correspondence are of the highest quality in terms of content, clarity, and accuracy.
- Represent CMC regulatory affairs on cross functional product teams and in health authority interactions.
- Provide regulatory assessments for manufacturing changes and quality compliance and participate in technical risk assessment exercises.
- Support the development and maintenance of regulatory templates, best practices, and procedures.
- Support hiring, leading the regulatory team.

About you

You have strong technical expertise and a proven track record as a proactive and collaborative leader at management level. You have strong regulatory experience, some of it managing people and you are qualified to a minimum of primary degree in a scientific/life science discipline with an advanced degree preferred (PhD, MS, PharmD).

You possess in-depth knowledge of global CMC regulations, you understand the evolving challenges and health authority expectations and you have significant experience of regulatory approval processes for pharmaceutical products globally. You have experience in IND, IMPD, BLA &, MAA filings.

You will draw from your many skills such as your ability to plan and organize, influence, form positive collaborative relationships, continuous improvement and customer focused mindset and problem solving ability.

Working at Eirgen – What to expect

At Eirgen, we have developed a diverse, people-centric, high performance culture where people are enabled to achieve their potential.

If you are working at Eirgen, then we think you've got something special. Our employees are high-performing and work as part of a cohesive team, they are dedicated people who are driven to succeed and are rewarded with competitive salaries and an attractive range of benefits including opportunities for career progression and continuing education.

Apply for the above role by sending your CV to opportunities@eirgen.com including the job title in the subject.