Head of Quality & Regulatory Compliance

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 will lead and manage the strategic and operational performance of the Quality & Regulatory Department and ideally also carry out the role of the Qualified Person.

You areas of responsibility will include:

Senior Leadership :

- Create and implement a best practice Quality vision, strategy, policies, processes and procedures to aid and enhance the EirGen business Value Proposition and performance
- Lead the Quality and Regulatory teams within EirGen to enable the highest standard of Quality and delivery of patient care to our valued partners. Inspire and motivate staff to achieve excellence and mentor them as they develop new skills.
- Develop the appropriate organisational structure, resource plans and culture, developing a high performing team that delivers exemplary compliance and innovative thinking in all elements of their delivery.
- Continuously evaluate the challenges faced by the business both internally and externally and take action to mitigate risks and develop opportunities for growth
- Develop and maintain strong relationships with internal and external stakeholders, regarding technical support for activities, striving for best in class products and business delivery to ensure a positive customer/patient experience.
- Along with Head of Quality at OPKO Health Miami to be responsibility for Corporate Quality oversight at OPKO Health and its subsidiaries
- As a member of the Eirgen SLT, partner with the team to develop, implement and lead company strategy, innovation and the delivery of exemplary business performance.

- Full responsibility for Budget planning and management to enable the overall delivery of annual financial objectives

QP Batch disposition:

- Certification as Qualified Person (Q.P.) and batch release as defined in Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC of sterile and non-sterile Human and veterinary clinical and medicinal bulk and packaged product

Functional Responsibilities

- Regulatory Compliance, SOPs, Annual reviews, Technical Agreements, License Database, and Dossier management Regulatory strategy for EirGen/OPKO products and in collaboration with co-development partners where applicable.
- Preparation of dossiers/INDs/IMPDs for EirGen/OPKO products and liaison with external contractors or co-development partners to submit dossiers in target markets
- Support for on-going Regulatory procedures
- Responsible for management of Clinical trials (PK/Bioequivalence) and safety/efficacy studies according to ICH/VICH GCP for EirGen/OPKO products and on behalf of Eirgen's customers where required
- Support existing products with respect to technical aspects or where Regulatory input needed
- Support out-licensing activities and commercialized OPKO products to promote EirGen Regulatory strategy

About you

You have strong technical expertise and a proven track record as a strategic and collaborative leader at senior management level. Qualified to a minimum of primary degree in a scientific or engineering discipline with Quality Management you possess a Post Graduate Diploma or Masters ideally in Pharmaceutical Technology/Quality Systems.

You have at least 10 years' pharmaceutical experience, preferably within the Quality Systems and Quality Assurance field of medicinal product manufacture, while Qualified Person capability is very advantageous. Experience with pharmaceutical packaging, oversight of Contract Manufacturing and Contract Development Manufacturing Organisations is preferable.

You possess knowledge of EU and FDA cGMPs, guidelines and also best practices have a good compliance record and experience preparing, facilitating and hosting regulatory inspections and customer audits, while prior experience of electronic document management systems is advantageous along with Project management skills.

You will draw from your many skills such as your ability to influence, form positive collaborative relationships, continuous improvement 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.

Closing Date is 31st July 2022.

Explore Energise Innovate