Regulatory & Clinical 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 will lead and develop EirGen's Regulatory and Clinical team and support clinical activities and the registration of EirGen/OPKO products (Human and Veterinary) in worldwide markets including US, EU and Japan.

You will ensure that project plans and milestones are delivered according to agreed timelines and co-ordinate department metrics around same, while managing department budget and spending in line with Corporate approved annual budgets.

You areas of responsibility will include:

- Project Planning/Co-ordination
    - actively plan clinical and regulatory requirements ensuring major milestone targets for each product are visible to all team members and key stakeholders to achieve on time market entry.
    - Collaboratively determine tasks and resources required to deliver each project milestone and deliverables
- Clinical Studies
    - Responsible for the design and management of all PK/bioequivalence studies (e.g. BE studies for generic products, BE/PK for value add generics and PK studies for new drug developments.
    - Design efficacy studies (Human and Veterinary) for in-house products and support OPKO Miami with efficacy studies as required.

- Responsibility for activities associated with the clinical trials including Regulatory approvals and IMP management.
- Act as company representative when liaising with clinical experts for such clinical studies.
- Support Business Development from a technical perspective as appropriate
- Together with the Business development Lead, ensure that all medical affairs enquires and support for customer marketing teams is delivered as appropriate.

- Patent management and regulatory strategies
  - Support the innovation team within EirGen with regulatory and clinical expertise, patent reviews and regulatory strategies as required.
  - Maintain the EirGen's patent estate quarterly reports and support the corporate patent office with requests.
- Regulatory Compliance
  - Oversee license maintenance support to customers, EirGen's Regulatory agents and internal departments within EirGen as per commercial individual agreements.
- Licensing Activities
  - Manage licensing activities for existing Marketing Authorisation applications in Europe, US, Japan, Canada and various markets Worldwide
- Dossier preparation
  - Manage dossier preparations module(s) 1-5 where appropriate for submissions to EirGen/OPKO target markets, including liaison with OPKO Miami, R&I, QC and Production as well as external experts where required.
- Strategic planning
  - Strategic planning of regulatory and clinical activities in target markets for EirGen's products
- Leadership
  - Coaching/mentoring-support members of team with problem solving and skills development to aid learning and early problem resolution
  - Assist with recruitment of team members in line with resource requirements on to job specification
  - Manage regulatory affairs budget and cost centre activities in line with overall budget and individual project budgets

About you

You have strong technical expertise and a proven track record as a proactive and collaborative leader at management level. Ideally you have 7yrs regulatory and/or clinical affairs experience, some of it managing people and you are qualified to a minimum of primary degree in a scientific discipline such as Chemistry, Pharmacy or Pharmacology.

You possess knowledge of cGCP and cGMP in pharmaceutical manufacturing, are familiar with EU and US Clinical trial legalization with significant experience of regulatory approval processes for pharmaceutical products globally. You have technical knowledge of the analytical/ formulation development of pharmaceutical Products (e.g. solid oral dosage forms) as well as the ability to

understand complex clinical terminology and the aptitude to learn new skills in the area of clinical research through working with external experts and CROs.

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.

Closing Date is 8th July 2022.

Explore Energise Innovate