

## Regulatory Affairs Officer

### JOB SUMMARY

**Location:** EirGen Pharma, Waterford

**Title:** Regulatory Affairs Officer

**Reporting to:** Senior Regulatory Affairs Officer and based at our R&D Centre on the Cork Road

### What will you be doing?

- **Working within a team, responsible for a number of key projects with the following as examples –**
  - **Dossier preparation** in collaboration with our in-house R&D team (our R&D capacity is substantial with over 60 in the team and expanding all of the time) to support our generics portfolio. Dosage forms include high containment, tablets, capsules, soft gel capsules, dry powder inhalers and injectables. Territories are diverse and include US, EU, Japan and many ROW territories.
  - Licensing support for OPKO's portfolio **new drug developments** – some are authorised (one with an NDA in the US) and others are at various stages of clinical development with EirGen as the CMC Centre of Excellence and Supply Chain. Working with our licensing partners in US, EU and Japan for these new projects. IND support, Paediatric development and involvement in PIPs and PMRs for EU and US.
  - **Biologics** – our new R&D facility houses a sterile fill finish line for manufacture of one of OPKO's new biological products. Our Regulatory team will be closely involved in dossier preparation for global registration on completion of the Clinical program.
  - **Veterinary** portfolio regulatory strategy – EirGen is developing a portfolio of **new drugs** for use in small animals with primary focus on US, followed by EU. Interaction with FDA and EMA on filing strategy and dossier content.

### What we need from YOU:

- You MUST be **passionate about Regulatory Affairs**
- A **degree** in Chemistry or Pharmacy (or a related discipline)
- Ideally you will have 1 -2 year Regulatory experience, however other CMC focused Pharma experience considered
- **Self-starter** who enjoys working in a **fast paced environment**
- You MUST enjoy **working as part of a team** and be fun and friendly

### What makes us different:

- We are a fun and exciting place to work!
- We have an incredibly broad range of products; Generics and New Drug developments; Human and Veterinary; we have a strong Clinical team in-house; substantial R&D capacity – all of which makes us very autonomous and self-resourced to deliver projects
- We encourage growth from within and like to promote our employees where we can
- We want to develop our employees and so we encourage them to undertake further training and courses wherever possible

- Diversity matters to us
- Our open door policy ensures that everyone's ideas are heard
- Not too many pharma companies can boast that they have a purpose built R&D Centre located in the sunny South-East of Ireland!
- Everyone sits together in the canteen – it doesn't matter who you are!

### **What's our culture like?**

- We have an active Sports and Social Club and they organise all sorts of fun events from trips to the cinema, to cycling the Greenway, to climbing the Wibit in Dunmore and everything else in between!
- Let them eat cake we say! Any excuse for cake and we're on it
- We like healthy stuff too, sometimes we even have salads with our Free Food Friday lunches
- We host all sorts of fun events to help raise money for our employee chosen charities – this even includes doing a spinning class!

### **What will you get if you work with us?**

Aside from having a great day at work, you'll also get:

- A great work environment with lots of fun
- A chance to work with like-minded people
- Be part of a team of people who work together to make life-saving products
- Work in Ireland's Pharma Company (SME) of the Year
- A great financial package to meet your knowledge and experience
- A company contributed pension
- Health Insurance
- Extra day's holidays
- Company sponsored events and nights out
- And lots of other stuff!!

### **Want to know more about EirGen?**

- EirGen Pharma was founded in 2005 by two budding entrepreneurs, Patsy and Tom who had buckets of pharma experience and a passion to grow their MBA programme idea
- The successful growth of EirGen attracted one of the world's best known pharmaceutical investors Dr Philip Frost and his company OPKO Health Inc. to purchase EirGen Pharma in May 2015 and go on to significantly invest in the Waterford sites.
- EirGen Pharma has two sites based on the outskirts of Waterford city, one is our Commercial Centre where the manufacture of our solid oral dosage forms occurs and the other is a purpose built, state of the art, R&D Centre which includes a sterile fill finish suite
- We are listed on the New York Stock Exchange
- We currently employ over 200 people and will continue to grow
- We are now **the International Research and Development and Supply Chain Centre of Excellence for OPKO Health Inc..**

At EirGen Pharma we are taking careers to new heights, and as a result have achieved some big milestones along the way:

- Winners of the Pharma Company of the Year (SME) in 2017
- In 2015 our high containment soft gel filling line became fully operational
- In June 2017 our office space at our R&D Centre opened and our Regulatory Team moved in!
- Our new R&D and Microbiology labs are due to open in April 2018 with full production planned for 2019 – so exciting times ahead!

In short, we are a **rapidly growing pharmaceutical company** and we need more great people to join our team to keep growing! We pride ourselves in **recruiting, developing, and retaining the best people**.

**Want to be a part of all of this?** Then send your CV to [HR@EirGen.com](mailto:HR@EirGen.com) to apply for our Regulatory Affairs Officer role today and become a fellow EirGener!!