



## Quality Assurance 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**

In this role you will manage and co-ordinate all Quality Assurance activities to support OPKO's products in Worldwide markets including US, EU and Japan.

The role includes management of the following:

#### **Material and Product Disposition:**

- Manage API, Excipients & Packaging Components material disposition
- Manage manufacturing batch documentation review
- Manage batch package preparation for QP release
- Be responsible for contract manufacturing organization management
- Generate metrics and manage visibility of metrics to Senior management
- All documentation relating to the material and product disposition process, cGxP, regulatory regulations and guidelines. Check own work/documentation and that of others for accuracy.
- Support the evaluation of quality deficiencies, incidents and possible complaints and the follow-up activities in the GMP departments. Escalation of critical Quality issues where required
- Ensure that all customer requests are dealt with within a reasonable timeframe & provide assistance to customer with regard to license renewals.

#### **Quality Compliance:**

- Manage QA support for all departments: Operations, Engineering, Finance, Regulatory, Business Development, IT, Research & Development



- Ensure that all work carried out is in compliance with the required standards conforming to company, cGxP, SOPs, regulatory regulations and guidelines, safety and environmental guidelines
- Support the maintenance of the EirGen Pharma Pharmaceutical Quality System to include: People, Premises & Equipment, Production, QC, Outsourced activities, Complaints & Product Recall, Self-Inspection
- Have ownership of deviation procedures and approval of investigations
  - Incidents & Deviations & Complaints
  - Out-of-Specifications, Out-of-Calibrations, Out-of-Trends
  - Planned Changes
- Manage Self Inspection Program

#### **Leadership and Continuous Improvement:**

- As part of the Extended Leadership Team attend meetings to ensure the effective running of the business
- Recruit, lead, develop, and manage the performance of the QA team, coach/mentor the team to aid learning and early problem resolution.
- Facilitate and lead a culture of continuous improvement
- Continuous promotion of a positive safety culture, leading by example

#### **About you**

You are educated to a minimum of degree level in a science discipline with a minimum of 5 years' experience in the pharmaceutical manufacturing industry in a quality assurance role or similar, with a minimum of 2 years in a quality leadership role with people management & cross-functional project management experience.

You possess extensive knowledge of PQS systems e.g. eDMS, eQMS, LMS and cGMP and GAMP guidelines, with customer & regulatory inspection preparation and support experience. Lead auditor experience is an advantage along with Customer & Regulatory Inspection hosting, preparation and support experience.

As a leader you will draw from your many skills such as people management, planning, multi-tasking, project and time management. You have the ability to form strong relationships and have influence cross functionally, you enjoy collaborating, gaining knowledge, continuous improvement and solving problems.

#### **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 further education.

***Apply for the above role by sending your CV to [opportunities@eirgen.com](mailto:opportunities@eirgen.com) including the job title in the subject.***