QA 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 for the company.

You will:

- Support the Head of Quality with the quality department function
- Maintain 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
- Manage and facilitate outside Inspections (Customer audits / Regulatory inspections)
- Perform manufacturing batch documentation review
- Manage Vendor Qualification
- Manage API, Excipients & Packaging Components material disposition
- Manage batch package preparation for QP release
- Be responsible for contract manufacturing organization management
- Generate metrics and manage visibility of metrics to Senior management
- Manage QA support for all departments: Operations, Engineering, Finance, Regulatory & Clinical Affairs, Business Development, IT, Technical Services, Research & Innovation

- Attend a number of cross functional team meetings as a Quality management representative including Area Management Team to ensure the effective running of the business
- Implement Safety requirements as per site documentation including SOPs, Safety Statement and COPs
- Continuously promote a positive safety culture by leading by example
- Manage workload of Quality Assurance group to meet Company goals
- Be primarily involved in the creation of Department goals
- Be primarily involved in the Department budgeting process
- Be responsible for the recruitment, leadership, development, appraisal and assessment of Quality Assurance members
- Implement performance evaluations for direct reports
- Elevate all critical Quality issues to the Head of Quality and Senior Management where required
- Participate in the evaluation of quality deficiencies, incidents and possible complaints and the follow-up activities in the GMP departments
- 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
- To perform additional tasks as agreed to support effective running of the business

About you

You are educated to a minimum of degree level in a science discipline with a post graduate qualification an advantage. You have a minimum of 7 years working in the Pharma industry, some of which must be in a QA role in a manufacturing environment as well as 3 years people management & cross-functional project experience, including team coaching and development. It would be an advantage if you are eligible to act as a Qualified Person under the permanent provision (2001/83/EC).

You have a strong compliance mind-set, expertise with cGMP guidelines relating to pharmaceutical manufacturing as well as working knowledge of EDMS (Electronic Document Management System) and ERP (Enterprise Resource Planning). 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 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 Thursday 30th June 2022.