QA Team Lead

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 support the Quality Assurance Manager with the development, implementation and maintenance of EirGen quality standards and systems to ensure that products comply with marketing authorisations, documentation, specifications and cGMPs. You will also lead and develop EirGen's group of Quality Assurance Officers to ensure project plans and milestones are delivered according to agreed timelines.

You will:

- Determine and track the tasks and resources required to deliver each project milestones and deliverables ensuring major milestone targets for each project are visible to all team members and key stakeholders to achieve on time market entry
- 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.
- Ensure high quality output – oversee job processes, tasks and work products to ensure freedom from errors, omissions or defects.
- Initiate action to correct quality problems and notify others of quality issues as appropriate. If a procedure does not exist, devise one, (through the appropriate channels); if a process needs amending, do so through the appropriate channels
- Coach/ Mentor - support members of team with problem solving and skill development to aid learning and early problem resolution
- identify and make recommendations for improvements as part of a team within or outside the department in order to ensure continuous improvement. Highlight opportunities for system optimisation to team members
- Ensure review of all QC and production batch documentation when required and correctly in order to achieve a high level of customer service and cGMP.
- Ensure preparation of Submission Documentation in support of licence applications

- Assist with the recruitment of new team members
- Ensure that SAP material changes are reviewed for correct updates and ensure SAP QA metrics generated monthly
- Ensure that all customer requests are dealt with within a reasonable timeframe and are extensive
- Ensure Commercial Meetings are attended and related trackers are maintained and timelines are agreed and achieved
- Ensure that Quality Management System meeting schedule is established and maintained and that QA are present to facilitate these meetings
- Ensure that the Batch documentation, Laboratory results and related Quality Systems are correct and approved prior to any QA/QP release required
- Ensure Self Inspection Program is maintained. Manage and lead/participate in outside Inspections (Customer audits / Regulatory inspections)
- Ensure requirements of EirGen Safety Statement are implemented and promote a positive safety culture by leading by example
- To perform additional team tasks as agreed to support effective running of the Business

About you

You are educated to degree level, preferably a Science degree incorporating Quality Assurance with a minimum of 5 years working in a QA role in a manufacturing environment. Ideally you will have previous team leader & cross-functional project experience, along with a supervisory management qualification and lead auditor qualification (not a requirement).

You have a strong compliance mind-set, familiarity with cGMPs relating to pharmaceutical manufacturing as well as working knowledge of EDMS (Electronic Document Management System) and ERP (Enterprise Resource Planning).

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 Friday 24th June 2022.