Senior Quality Officer

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?

A growing and innovative company based in Waterford, EirGen Pharma develops and supplies specialty care medicines to patients in more than 50 countries worldwide. Our guiding principle is to improve and enhance the lives of patients, whether they be reached directly or through our contract manufacturing and development customers across the pharmaceutical industry.

Eirgen's Waterford campus consists of a state-of-the-art and globally-accredited manufacturing environment which provides tableting, capsule, soft gel manufacturing and packaging capabilities. Our R&D function accommodates our development and analytical scientists working on the next generation of treatments for the company and its clients.

About the Job

In this role you will primarily support the Eirgen site to ensure compliance to all industry standards, and regulatory requirements. You will drive the proactive site Quality Risk Management (QRM) Quality System and influence at all levels of the organization to ensure an easily understood, repeatable compliance level can be achieved. Additionally you will also be actively involved in other key Quality System elements such as Supplier Quality Management, Market Complaints etc.

You will:

- Be responsible for developing, managing and improving the Site QRM Program and communicate status of same to all levels of the organization.
- Develop training programs for the site on all aspects of QRM and deliver the same to areas & identified SME's.
- Facilitate site FMEA's and major risk assessments in order to drive GxP compliance levels in a proactive manner.
- Manage the site QRM Governance program in order to support all site to escalate and communicate known risks, ensure mitigation plans are identified and tracked and drive a proactive risk approach on site through monitoring, measuring, direction and communication.
- Drive and manage the site Regulatory Intelligence program. Ensure the site is compliant to all regulatory changes through a controlled process that ensures an assessment of the gaps by the relevant SME's and tracking of closure of all gaps.
- Develop, manage and continuously improve the site knowledge management program to ensure that all levels and areas of the organization have access to current regulations and industry guidance documents to support improvements and compliance across the site.
- Manage all site licenses, GMP certificates, MIA's
- Participate in site audit activities as required.
- Continuously identify and implement system improvements.
- Ensure that all work carried out is in compliance with the required standards conforming to all site requirements and cGxP regulations and guidelines, safety and environmental guidelines

- Manage the site Supplier Quality Management program in order to ensure that suppliers are selected, approved and monitored in a compliant and efficient manner.

About you

You are qualified to degree level (or equivalent) preferably in Science, engineering or a related discipline with at least 5yrs experience in a Quality Assurance and/or an Engineering role in a Pharma environment. You ideally have previous formal training in QRM Facilitation and experience with a QRM program is desirable. You have a comprehensive understanding of site required regulations and industry standards and technical knowledge of analytical/manufacture of pharmaceutical products. Demonstrated experience managing key aspects of a Quality Management System is preferred. Lean Six Sigma training is desirable but not essential.

You possess excellent written & verbal communication skills, including strong technical writing skills - you present complex data in a clear, understandable format. You have a quality driven mind-set with strong attention to detail and problem solving ability and work effectively on your own as well as with others - previous experience in leadership roles, direct or indirect would be an advantage.

You are results oriented and possess energy and drive. You will draw from many skills including adaptability, planning, multi-tasking and time management. You have the ability to form positive relationships and enjoy collaborating, gaining knowledge, continuous improvement and applying innovative ideas.

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.