Quality Systems & Compliance 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 ensure the compliance of all Quality Systems and you will support the Head of Quality with activities associated with the regulatory compliance activities of Eirgen/OPKO's products in Worldwide markets including US, EU and Japan.

The role includes management of the following:

Quality Systems:

- Eirgen Quality System to include: Documentation, Training, CVS Governance, Supplier Management, QUMAS eDMS, TrackWise eQMS and LMS
- Data bases for the quality system, metrics and quality trending reports, compilation and distribution of departmental monthly, quarterly and annual metrics
- All documentation conforming to company, cGxP, regulatory regulations and guidelines. Check own work/documentation and that of others for accuracy. Site documentation archival and retrieval processes
- Department budgeting process
- 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.

Compliance:

- Schedule, prepare and ensure approval of annual Product Quality Reports for all commercial product as per defined schedule and cGMP's, review reports that are received from third party contract facilities
- Assist Quality department with:
  - Completion of change controls and reviews to facilitate QP release in a timely manner
  - Self-inspection program as per the defined schedule. Preparation & participation in outside Inspections (Customer audits / Regulatory inspections)

Regulatory Compliance:

- Strategic planning of regulatory compliance activities to support QP release of products, including initiation and/or progression of all regulatory change controls
- Ensure regulatory compliance of all customers registered details with internal documentation
- Ensure that internal procedures meet the regulatory requirements to maintain our licences
- Facilitate the renewal or creation of Manufacturing Licences and associated fees.

Leadership and Continuous Improvement:

- Attend meetings including Extended Leadership Team to ensure the effective running of the business
- Recruit, lead, develop, and manage the performance of the 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 and have pharmaceutical experience in quality and/or regulatory affairs, some of which must be in a 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.

Apply for the above role by sending your CV to opportunities@eirgen.com including the job title in the subject.