Pharmacovigilance Lead

Reach your career goals with Eirgen Pharma, your future could be here!

About Eirgen Pharma

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?
Founded in 2005, Eirgen Pharma employs over 180 people in Waterford. We combine the agility of a small company with the ambition to deliver high-quality medicines globally — all within a collaborative, people-focused culture.

About this Opportunity

You will establish, implement, maintain and continuously improve Eirgen Pharma's Pharmacovigilance (PV) System, ensuring compliance with applicable European Union, Irish Health Products Regulatory Authority (HPRA), United States Food and Drug Administration (FDA), and other international pharmacovigilance requirements.
The Pharmacovigilance Lead will provide oversight of all product safety activities throughout the product lifecycle, ensuring patient safety while maintaining inspection readiness and regulatory compliance

Key Responsibilities:

- Establish, implement and maintain the company's Pharmacovigilance (PV) System in compliance with EU, HPRA, FDA and other applicable regulatory requirements.
- Manage the Pharmacovigilance Quality Management System, ensuring inspection readiness and continuous compliance.
- Develop and maintain PV procedures, quality documentation, the Pharmacovigilance System Master File (PSMF) and key performance metrics.
- Manage the collection, assessment, processing and regulatory submission of adverse event reports, ensuring compliance with reporting timelines.
- Conduct signal detection, benefit-risk assessments and risk management activities, including the maintenance of Risk Management Plans where required.
- Coordinate the preparation and submission of aggregate safety reports (including PSURs/PBRERs and DSURs) and support regulatory safety responses.
- Perform medical literature surveillance and ensure reportable safety information is identified and processed appropriately.
- Monitor evolving Pharmacovigilance legislation and implement regulatory changes to maintain compliance.
- Collaborate with Regulatory Affairs to support marketing authorisations, product lifecycle activities and regulatory submissions.
- Establish and manage Pharmacovigilance Agreements and oversee the performance and compliance of external vendors and service providers.
- Support audits, inspections, CAPAs and quality risk management activities, maintaining inspection-ready documentation.

- Provide Pharmacovigilance expertise, training and guidance across the organisation while promoting a strong patient safety and compliance culture.
- Drive continuous improvement initiatives to enhance Pharmacovigilance systems, processes and business performance.
- Comply with all Health, Safety and Environmental requirements and undertake additional duties as required to support the Quality function.

About you

- Degree in Pharmacy, Pharmaceutical Sciences, Life Sciences or a related scientific discipline.
- Minimum 5 years' Pharmacovigilance experience within the pharmaceutical industry.
- Proven experience in post-marketing Pharmacovigilance, including adverse event case management.
- Strong knowledge of EU GVP and applicable EMA, HPRA and FDA Pharmacovigilance requirements.
- Experience developing and maintaining Pharmacovigilance Quality Management Systems, SOPs and quality documentation.
- Experience preparing for and supporting Pharmacovigilance audits and regulatory inspections.
- Proficiency with Pharmacovigilance databases (e.g. Oracle Argus, ARISg, Veeva Safety or equivalent) and MedDRA coding.
- Experience with vendor oversight, Pharmacovigilance Agreements and support for EU QPPV activities is advantageous.

Why Join Eigen Pharma?

- You will work as part of a collaborative team, contributing to high-quality delivery in a fast-paced, GMP-regulated environment
- Collaborative and quality-driven environment
- Excellent benefits, pension, health insurance, social club, canteen facilities

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