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Director of Pharmacovigilance

Hiring organization
BioLink 360

Employment Type
Full-time

Job Location
San Diego, CA

Date posted
January 16, 2025

Description

Position Title: The Director of Pharmacovigilance
Location: San Diego, CA
Position reports to: VP and Head of Safety
Salary Range: 180K-240K

This person will be responsible for all activities related to the Pharmacovigilance Quality Management System oversight as well as audit and inspection readiness globally. In this role and leading compliance & training within the Safety & PV teams and cross functionally to drive global compliance. In addition, the person in this role will also provide strategic input and implementation for pharmacovigilance activities and projects, identify and communicate compliance risks, oversee action plans to mitigate those risks and lead, oversee and develop the highest level of operational excellence of corrective and preventative action deliverables to ensure timely compliance.

Responsibilities

- Oversees global PV compliance and PV quality oversight for all aspects of the global Quality Management System (QMS) including Deviations, CAPAs, and KPIs
- Works closely with clinical and commercial QA, with inspection activities and serves as the point person with HA (FDA, EMA, MHRA, HPRA, and Health Canada).
- Collaborates with Global Regulatory Compliance, Global Regulatory Affairs, Global Drug Development, Commercial, Market Research, Legal and other cross-functional teams.
- Oversee the planning, execution, and delivery of CAPA strategies/plans for the remediation, correction, and prevention of recurrence of those significant quality events.
- Develop and execute analytical and tactical strategies aligned to business projects, milestones, and policies to ensure timely delivery.
- Develop, implement, and maintain reporting of metrics that enable the monitoring and optimization of effectiveness, including dashboard and/or standard reports and Scorecards

Qualifications

- Advanced Degree in Life Science disciplines. Medical Degree (MD), PharmD, or similar
- 10+ years of experience gained in Pharmacovigilance, Clinical Research, or Clinical Development within the Pharmaceutical industry and/or CRO including significant experience in operating in a global pharmacovigilance organization.
- 5+ years leadership experience.
- Demonstrated knowledge of regulatory agency requirements regarding drug safety and an understanding of general drug safety methodologies.
- Ability to comprehend and synthesize complex data and experience in the

identification, analysis, and implementation of programs and procedures required to achieve corporate objectives.