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Director of Pharmacovigilance & Regulatory Affairs

Hiring organization
BioLink 360

Employment Type
Full-time

Job Location
Boston, MA

Date posted
March 21, 2023

Description

Location: Boston HQ, on site

About the Company

Our client is a market leader in diagnostic imaging agents, a global company with under 1000 employees, with HQ in Boston. The person hired will direct all global pharmacovigilance activities and safety reporting for all marketed products, and oversee internal work team activities, and external contractors, including global CRO(s), effectively marshalling resources in a matrix organization. He/She will oversee management of the global CRO pharmacovigilance partners and associated staff, and ensure the training, education and performance of these contract staff, as well as internal staff. This person will collaborate with and manage the Pharmacovigilance Medical Director.

There is a Pharmacovigilance Medical Director and a small US-based regulatory team and in-country contract resources in international regions that will report to the VP.

Responsibilities

This VP will lead global regulatory function and develop regulatory strategy for new product development and registration as well as life cycle management.

Essential Functions

- Directs all global pharmacovigilance activities and safety reporting for all marketed products. Oversee internal work team activities, and external contractors, including global CRO(s).
- Oversees management of global CRO pharmacovigilance partner and associated staff, ensuring the training, education and performance of team.
- Develop the global regulatory and pharmacovigilance strategies for all projects and products in collaboration with senior R&D, medical and commercial leadership.
- Develops and monitors key metrics of performance and compliance and monitors the dynamic progression of projects through the regulatory submission process.
- Manages resources allocated to ensure efficient utilization consistent with priorities.
- Champions processes and procedures to facilitate achievement and collaborative communication within function and with other organizations.
- Prepares and reviews technical documentation in support of regulatory submissions and approves research reports, specifications and non-clinical sections of regulatory filings.
- Leads the regulatory assessment of in-licensing and product acquisition opportunities and business development initiatives.

Qualifications

- BS is required, or MS, PharmD, PhD/MD preferred
- 12+ years in Regulatory Affairs/Pharmacovigilence