Vice President, Pharmacovigilance

Do you want to be part of building a fully integrated biopharmaceutical company together with a team of highly skilled colleagues who are passionate about developing best-in-class therapeutics that address significant unmet medical needs? Then Ascendis Pharma is committed to support your personal development on our journey towards becoming a leading rare disease company.

Ascendis Pharma is looking for a Vice President, Pharmacovigilance to join our team. This is an exciting opportunity to join a rapidly growing, innovative company!

Position Summary

The VP Pharmacovigilance will build and lead the Pharmacovigilance group, provide hands-on medical monitoring, and strategic leadership for assigned investigational and marketed products. This individual will oversee the operational infrastructure required to oversee all aspects of adverse event collection, processing and reporting from clinical trials, post marketing and other sources, as applicable. This critical role provides strategic guidance to other functions (such as Data Management, Biometrics, Clinical Operations, Clinical Development) involved in adverse event collection and safety management throughout the lifecycle of Ascendis therapies. The role will be based in Palo Alto and will report directly to the Chief Medical Officer.

Key Responsibilities

- Leads and directs all aspects of pharmacovigilance activities for assigned investigational and marketed products
- Responsible for developing, executing and maintaining risk management strategy for assigned products
- Authors, reviews and provides input for drug-safety related regulatory reports and clinical study documents including periodic aggregate reports, case series analyses, regulatory submission documents
- Contributes to the development of internal processes including SOPs, Guidelines and Work Instructions
- Acts as medical and scientific subject matter expert for the pharmacovigilance capabilities build of a growing function within the Company
- Leads the labeling activities for the safety sections of the assigned product/indication
- Leads the creation of responses to safety questions from Regulatory Agencies for the assigned products/projects, and reviews and/or contributes to responses for safety questions for non-assigned products/projects
- Contributes to the Safety Medical Teams for meetings associated with assigned products/indications
- Designated Subject Matter Expert for medical questions related to processing ICSRs in partner audits and regulatory inspections

Knowledge, Skills and Experience

- MD (or equivalent)
- Minimum 15 years of experience in medical drug safety in the pharmaceutical industry and demonstrated results in managing the multiple facets of clinical safety and pharmacovigilance

- Substantial knowledge and experience with drug safety medical assessments in clinical trials and post market
- Experience in developing risk management strategies and writing risk management plans
- Experience and extensive working knowledge with Drug Safety Databases, data analysis tools, and document management systems
- Understanding of how global drug safety related regulations are applied
- Experience in leading cross functional drug safety team and cross-departmental interactions with clinical development, medical affairs, regulatory affairs, and commercial groups
- Excellent knowledge of drug development process
- Strong leadership and oral/written communication skills
- Ability to travel up to 20% of the time domestically and internationally

Want to apply? Please send your resume to HumanResources@ascendispharma.com. Please write "Vice President, Pharmacovigilance" in the subject field.