Vice President, Global Regulatory Affairs and Quality

Remote

Summary

Reporting to the Chief Development Officer, the VP, Global Regulatory Affairs and Quality provides strategic and operational leadership for the Regulatory Affairs and Quality activities within the company.

Responsibilities

- Develops and executes Regulatory and Quality strategies, policies, guidelines, programs, and procedures for Sierra.
- Provides leadership in product quality problem solving resolution efforts across the organization.
- Represents company interests with national government agencies, industry associations and/or other organizations for the purpose of advancing programs and ensuring compliance with legislation, regulations and/or guidelines that impact the business in both the therapeutic and the clinical diagnostic market.
- Oversees preparation of company regulatory submissions including IND/CTA, IMPD and NDA strategies
- Oversees preparation of regulatory agency responses.
- Works closely with senior leaders from other functional disciplines to ensure that strategic business objectives are achieved through the sharing of knowledge and expertise.
- Anticipates regulatory obstacles and emerging issues throughout the pharmaceutical product development lifecycle and develops solutions in consultation with members of regulatory, quality and related teams.
- Designs and implements appropriate metrics to track performance and apply counter measures to close any gap.
- Ensures compliance to cGMP’s and other regulatory agency requirements and company initiatives.
- Reviews and approve change controls including manufacturing processes and procedures, analytical procedures, and related batch records/testing SOP’s; assures appropriate reports are issued, approved, and implemented.
- Contributes to project teams by providing regulatory expertise and guidance on regulatory matters.
- Ensures timely and high-quality execution of Regulatory deliverables through effective management of Regulatory Affairs personnel and by working to ensure appropriate cross-functional coordination is occurring for effective completion of Regulatory submissions and documents.
- Recruit, develop, and mentor personnel in Regulatory Affairs and Quality
- Budgetary responsibility for Regulatory Affairs and Quality; prepares department budgets and identifies appropriate external resources as needed.
- Other related duties as assigned.

Qualifications and Requirements

- Advanced degree in the life sciences, or the equivalent combination of education and experience.
- Minimum of 10 years' experience in the pharmaceutical/biotechnology industry with Regulatory Affairs/Quality Assurance or related function(s).
- Ability to pragmatically balance strategic and operational regulatory and quality requirements, effectively interpreting guidelines within the context of company objectives.
- Good communicator, able to work in a diverse team, providing hands on leadership.
- Hands-on experience with regulatory submissions including IND's/CTA's, IMPD's and planning for future NDAs/MAAs.
- Proven track record of successful interactions with FDA/MHRA and other global regulatory authorities.
- Extensive knowledge of cGXP regulations and current industry trends as related to pharmaceutical products.
- Thorough understanding of the CFR and FDA/ICH guidelines and cGXP's, as they pertain to pharmaceuticals, diagnostics and other related aspects of novel drug development.

How to Apply

To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email.

We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.