Senior Vice President, Clinical Development
Remote

Summary
Reporting to the Chief Medical Officer, the Senior Vice President, Clinical Development provides strategic and operational oversight and direction to the Clinical Science and Biometrics team in support of NDA/MAA enabling activities and other development activities.

Responsibilities

- Provides day-to-day practical, as well as strategic guidance for clinical programs/teams and ensures that the design, implementation and conduct of our clinical programs provide unambiguous data and information that allows for clear decision making and advancement of our development efforts.
- Provides leadership and direct oversight for biometrics and clinical science.
- Provides leadership for and participates in the preparation of the CSR’s and other CTD related documents relevant to the NDA / MAA submission preparation activities.
- Provides leadership for and participates in the regulatory review process including playing a lead role in ODAC preparation.
- Provides leadership for the Product Development Team (PDT) overseeing, leading, and contributing to the clinical development plan.
- Develops and executes the clinical development strategy for company assets (e.g., life cycle opportunities for momelotinib and development plans for assets other than momelotinib) based on available clinical and preclinical data, while working closely with regulatory, clinical, scientific and business colleagues in the development of such a plan.
- Collates, interprets, presents, and disseminates clinical data and outcomes to stakeholders internal and external to firm Including preparation of materials to senior management or external advisors, ensuring effective presentation of data.
- Directs the analysis and interpretation of clinical data for achievement of safety and efficacy endpoints and optimization of regulatory outcomes based on available data.
- Participates in regulatory interactions, including FDA and EMA.
- Participates in launch activities and oversees the clinical science and/or biometrics support required for successful, effective, and compliant Medical Affairs efforts.
- Plays a key role in medical meeting preparation, abstract generation and presentation and manuscript preparation.
- Builds and fosters relationships with medical and clinical communities, including patient advocacy groups, through participation in or leading of Clinical Advisory Boards and other forms of strategic consultation.
- Develops the strategy and execution plans for expanded access program.
- Assists with in-licensing, evaluating, and assessing clinical development strategies for new technologies and potential new pipeline products. Participates in diligence activities as required.
- Collaborates closely with cross-functional colleagues such as those in Clinical Operations, Pharmacovigilance, Regulatory, Program Management, Clinical Quality, and
others to optimize effectiveness of our programs and to facilitate problem solving, risk mitigation efforts.

- Mentors and develops team members in building a successful and scalable organization for the future.
- Ensures alignment with CDO in the implementation and execution of the strategy.
- Other related duties as assigned.

**Qualifications and Requirements**

- MD, or the equivalent
- Minimum 10 years of drug development experience with hematology or oncology clinical development experience strongly preferred.
- Phase III drug development and NDA/MAA submission experience
- Experience working with FDA and related regulators required.
- Hands-on leadership experience is imperative to effectively oversee a multifunctional team.
- Ability to work effectively in a rapidly changing and scaling environment and thrive under a fast pace and add substantial value to the organization.
- A high level of self-awareness and emotional intelligence is required for this position with strong personal credibility and excellent communication skills.
- Ability to work effectively in a remote employee-based company.
- Ability to travel as required and necessary

**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.