Sr. Director/VP Regulatory Affairs and Quality Management

The incumbent will lead the strategic and operational aspects of regulatory and quality functions for Seelos Therapeutics, Inc. The incumbent will work closely with senior management to establish regulatory strategies for global and U.S. submissions of Seelos Therapeutics' pipeline products.

The role is responsible for interacting with regulatory agencies, initiating and managing IND's and NDA's and maintain a compliant regulatory and quality environment.

This position is based out of our New York City headquarters.

RESPONSIBILITIES

- Develops and implements regulatory strategies for filing of IND's NDA's CTA's. MAA's for Seelos Therapeutics pipeline products and ensures regulatory documents are filed on time
- Interact and negotiate with senior FDA, EMA, and other international regulatory agencies for regulatory submissions, agency meetings (Type A-C, preclinical, end of Phase II, pre-NDA, scientific advice etc.)
- Initiates, maintains and archives all agency interactions verbal and written responses and agreements and leads development of company response to regulatory comments
- Leads interactions with project team members, consultants, CMOs, CROs, and regulatory authorities to ensure regulatory paths are clearly defined and milestones are met leading to successful filings and approvals
- Lead all aspects of regulatory submissions, including the review of technical documents (clinical and non-clinical information), development and tracking of submission timelines, and preparation of regulatory content to ensure compliance with guidelines
- Perform risk assessments, gap analyses, and develop and implement internal controls to mitigate compliance risk
- Accountable for the delivery of regulatory milestones including assessment of the probability of regulatory success together with risk mitigation measures
- Assists with adverse event reporting and evaluates adverse events to determine root causes, identify corrective actions and prevent recurrence
- Lead the implementation of quality initiatives to support GXP processes, GMP compliance and overseeing GCP and GLP requirements across the company and interact with relevant regulatory agencies
- Establish quality systems and procedures that ensure compliance with ICH guidelines and regulations
- Develop/maintain internal and external audit programs to satisfy contractual and regulatory requirements for GXP
- Oversee quality review of documents for regulatory submissions, validation and qualification plans and inspection readiness planning for global and U.S. submissions
- Initiate and deploy relevant SOP's to ensure regulatory and quality compliance commensurate to current regulations
- Guide cross functional departments of current and new regulations and ensure quality and regulatory compliance across the company and product portfolio

QUALIFICATIONS

- Advanced degree in a relevant scientific discipline
- Demonstrated successful management of IND's, CTA's NDA's etc. for global regulatory submissions
- 15+ years' progressive global and U.S. experience in regulatory and quality within the pharmaceutical and/or biotech industry
- Track record of communicating and presenting regulatory strategy to agencies and gained approvals
- Extensive knowledge and experience in quality compliance

EQUAL EMPLOYMENT OPPORTUNITY

Seelos ensures that all its staff members comply with federal, state and local legislation, government regulations, and corporate policies regulating affirmative action and equal opportunity.

Seelos hires, trains, promotes, compensates, transfers and administers all employment practices without unlawfully discriminating on the basis of sex (including pregnancy, childbirth, or related medical conditions), race, age, religion, color, sexual orientation, gender identity, protected veteran status, national origin, disability, or any other basis prohibited under applicable law.

It is also the company policy of Seelos Therapeutics to comply with applicable legal requirements concerning reasonable accommodations for religious beliefs or practices and for persons with covered disabilities.

COME GROW WITH US - ADD TO THE VALUE OF SEELOS

Seelos Therapeutics places significant value on fostering and enhancing the talents and growth of our colleagues - both the person and the professional.

We ensure our teams have all the resources they need to maximize their potential.

Are you ready to make a real difference and help us advance the development of our assets and our organization?

Discover what opportunities await you at Seelos.

We invite you to email Seelos at info@seelostx.com.

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