Director of Regulatory Affairs

IDEAYA is an oncology-focused biotechnology company committed to the discovery of breakthrough synthetic lethality medicines targeting DNA damage and repair for genetically defined patient populations and for enhancing immunotherapy response, and immuno-oncology therapies targeting the tumor micro-environment. IDEAYA, located in South San Francisco and La Jolla, California, has assembled leading scientists and advisors with extensive knowledge and expertise in cancer biology and small molecule drug discovery. For more information, please visit www.ideayabio.com.

IDEAYA Biosciences is seeking a South San Francisco based experienced, motivated, outgoing leader to head Regulatory Affairs. This person will be responsible for development of US and rest of world regulatory strategy for IDEAYA's oncology pipeline and to represent Regulatory Affairs on project teams. The individual must have knowledge of regulatory requirements in major regions (US, EU) with responsibility to form a global strategy, including in Asia; Develops and maintains communications with FDA and coordinates interaction with regulatory agencies worldwide.

The successful applicant will join the senior management group of the Development department and will report directly to the Chief Medical Officer. The ideal candidate will enjoy working within an open, multi-disciplinary team, partnering closely with Research, and possess a passion for building collaborative teams.

Job duties and responsibilities will include but are not limited to:

- Develops regulatory strategic plans for project teams. Works with project teams to resolve complex project issues. Utilizes regulatory expertise and knowledge of regulatory requirements and regulations to strategically interpret, plan, and communicate requirements to ensure governmental approvals are obtained. Represent IDEAYA before regulatory authorities.
- Assist in the design and interpretation of results for Clinical Studies required for Regulatory Approvals.
- Responsible for filing of CTA/IMPD/IND/BLA submissions. Sets strategy for submissions of product registration documents to health authorities worldwide. Interacts with other line functions in the preparation, review, and completion of documents for regulatory submissions.
- Responsible for keeping management team informed of regulatory status of products and significant regulatory issues. Able to present and implement project related regulatory strategy with all Project Teams. Assures compliance with project team timelines and milestones.
- Effectively plan, organize, and conduct (or supervise) formal meetings with regulatory agencies. Interact with key personnel in regulatory agencies to ensure the review and approval of development plans, the timely resolution of issues, and the approval of marketing applications.
- Provide counsel, training, and interpretation of FDA's and other regulatory authorities' feedback, policies and guidelines to IDEAYA and assist as a liaison between IDEAYA and regulatory authorities.
- Provide interpretive analyses of complex regulatory guidance documents, regulations, or directives that influence IDEAYA's products and operations. Advise personnel in other departments regarding their applicability and impact.
- Manage a team in Regulatory Affairs & Operations and have working knowledge of the Regulatory Operations function and submission logistics
- Have working knowledge of regulatory issues that pertain to CMC

Qualifications

- Bachelor's degree in a Life Sciences discipline or equivalent, M.S. degree preferred.
- Minimum of ten (10) years of experience in clinical regulatory and high potential for progressive senior leadership roles.
- Proven ability to develop and manage a high performance regulatory team focused on accountability and meeting and exceeding expectations.
- Excellent track record for product approvals in the US and EU
- Extensive experience in cGMP and other Regulatory (CMC, preclinical) compliance requirements.
- Possess a broad knowledge of biopharmaceutical manufacturing and operations.
- Balance of strategic thinking and strong analytical skills with ability to execute.
- Experience with international regulatory submissions and an understanding of worldwide guidelines and regulations preferred.
- Detail oriented and results driven with strong written, verbal communication and presentation skills.

Essential Skills and Abilities:

- Demonstrated excellence in regulatory liaison/strategy
- Strategic thinking, leadership skills, assertiveness, strong technical background, and excellent negotiation and project management skills as evidenced by past performance on drug development project teams
- Able to analyze worldwide regulatory requirements to synthesize a global regulatory development strategy as evidenced by past regulatory experience
- Excellent interpersonal skills
- Excellent communication skills (verbal and written) as evidenced by a demonstrated ability to prepare complex documents / submissions and to give presentations
- Management experience is preferred
- Ability to work independently
- Ability to travel (approximately estimated 20% travel required)