Associate Director/Director, Regulatory Affairs

About IDEAYA Biosciences:

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

IDEAYA Biosciences is seeking a South San Francisco based, experienced, motivated, outgoing leader to join our Regulatory team. The Associate Director/Director of Regulatory Affairs will prepare and manage regulatory submissions and other regulatory-related documents, and oversee Medical Writing as our company expands.

Location: South San Francisco, California

Reporting Relationship: Reports to the Head of Regulatory Affairs

The Opportunity:

This individual will have a solid understanding of FDA and global Health Authority regulations and ICH guidances, and experience with regulatory submissions including INDs, international clinical trial applications, and marketing applications in Common Technical Document format. Excellent written and effective verbal communication skills, proficiency in project management, and flexibility/adaptability to work in a fast-paced environment are also essential.

Major Duties/Responsibilities

- Prepare, manage, and maintain regulatory submissions (e.g., INDs, CTAs, amendments, safety reports, DSUR/annual reports, meeting packages, etc.) in accordance with applicable regulations. Translate regulatory requirements into practical, workable submission plans; develop and maintain timelines; coordinate internal/external authoring/review/comment adjudication and finalization (submission and archival).
- Coordinate efforts with external publishing vendor, if appropriate, for building submissions in the CTD structure and filing the output via the ESG (Electronic Submissions Gateway).
- Initiate and/or contribute to local process improvements which have an impact on Regulatory Affairs, Quality Assurance, Clinical Operations, and other departments.
- Review and communicate current and emerging regulatory requirements (e.g., US and international regulations and guidelines).

- Author and review standard operating procedures (SOPs); ensure SOPs comply with current regulatory requirements and provide regulatory support for quality assurance efforts.
- Implement regulatory strategies to facilitate progress for programs in all phases of development.
- Participate on cross-functional project team(s) and provide feedback on regulatory issues.
- Establish timelines for regulatory submissions related to INDs/CTAs, including nonclinical, clinical, and CMC activities, while planning for global NDAs/MAAs.
- Participate in interactions with regulatory agencies and external service providers.
- Assist teams with the development, review, and finalization of briefing documents to FDA or health authorities, conduct meeting rehearsals, and participate in regulatory meetings.

Personal Strengths:

- A proven self-starter and team player with strong interpersonal skills who establishes & nurtures highly effective relationships with colleagues and key stakeholders to support and advance project goals and objectives
- Critical thinker with a solutions-oriented mindset
- Self motivated to work effectively in a dynamic environment
- Possess strong organizational skills and conflict resolution abilities

Professional Requirements:

- Bachelor's degree in a scientific discipline or 10+ years of regulatory documentation and operations experience
- Regulatory Affairs Certification preferred
- Solid understanding of FDA regulations and ICH guidance as well as comprehension of the drug development process
- Excellent Computer Skills in Word, Excel, PowerPoint, and Acrobat
- Familiarity with eCTD publishing software
- Experience with pharmaceutical regulatory submissions and managing major regulatory filing(s) such as IND/CTA and NDA/MAA