Director, Global Regulatory Affairs, Waltham, Massachusetts

Responsibilities:

The **Director, Global Regulatory Affairs** will provide regulatory expertise regarding scientific and related fields such as preclinical, clinical research, CMC, business development and commercial as well as product development support with external partners. Participates in project teams to provide regulatory strategies and able to lead in regulatory scientific review of submissions including NDA, IND, IDE, MAA, CTA, CTD, NDS submissions. An experienced global regulatory affairs professional with a complete knowledge and understanding of pharmaceutical development life cycle management and a solid understanding of medical devices and combination products will be a plus. This position will be involved in the development and implementation of a consolidated global regulatory strategies to secure and maintain market access for the assigned indications through all developmental phases, registration (including combination products) and post-marketing/life cycle management (e.g. variations, renewals, labeling) activities. The incumbent responsibilities will include establishing and maintaining effective relationships with regulatory agencies, especially the FDA, EMA and PMDA and knowledgeable in in global electronic submissions for marketing applications such as eCTD publishing.

The Director should have strong leadership skills with a clear vision, able to motivate, operate in a nimble high performance team, and create quality regulatory submissions with a focus on delivery with excellence. The Director routinely works cross-functionally with internal departments and is expected to provide global strategic and operational leadership for the planning, management, support and execution of regulatory activities. They will be expected to lead and manage a strong and diverse team, coordinate and supervise development and implementation of regulatory processes and interact with external resources and consultants on regulatory related issues to manage timely and effective document preparations and management that meet all emerging global requirements.

- Expected to be responsible for the overall direction, coordination, implementation, execution, control and completion of regulatory development projects ensuring compliance to regulations, consistency with company strategy,
- Develops and executes regulatory strategy for development of the company's programs aligned with company's objectives that will creatively position for expeditious product review and approval globally
- Leads and manages interactions with project team members, consultants, contractors and regulatory agencies to ensure all project/programs have clearly defined regulatory paths and milestones leading to successful filings and approvals. Works collaboratively across functions and teams to develop and implement the Company's strategies
- Ensures that regulatory strategies are executed in compliance with current, applicable regulations and standards
- Leads effort to produce regulatory submissions/documents and prepares, reviews, revises and approve regulatory submission documents and communications including: Investigator Brochures, Annual Reports, Orphan Drug Applications, Rare Pediatric Diseases, Breakthrough Therapy, and Background Documents for Regulatory Authority meetings

- Assess project plans and timelines and ensures all projects are appropriately prioritized and key goals are met on time
- Ensure compliance with regulations and guidelines related to regulatory submissions, product launch, labeling, advertising and promotion and reporting requirements in USA, Europe, Japan and other regions Participate in counselling and advising senior management on status of global regulatory strategy, tactics, procedures and practices and providing critical risk assessments and alternate strategies
- Ensure the Company is kept current with all new regulatory requirements, evolving global regulatory environment, communicate and implement appropriate changes and provide guidance on the implications of new/updated requirements
- Provide strategic and tactical decisions regarding regulatory filings and be responsible for timely regulatory submissions of high quality in all formats
- Maintains current information and awareness of regulatory intelligence, including regulatory agency guidance, procedures and provides appropriate updates
- Anticipates global regulatory changes and continuously develops proactive strategies accordingly
- Interacts with regulatory agencies and ensures effective communications with health authorities
- Provide regulatory support to business development activities such as due diligence initiatives and regulatory assessments of new business opportunities including risk assessment as required
- Develop and grow the regulatory department with coaching and mentoring department staff

Qualifications:

- Doctorate, Master's, or Bachelor's degree in a life science field (Biology, Chemistry, or Pharmaceutical sciences) with required 12+ years' experience in pharmaceutical or biotech industry in multiple phases of development (with both big and small company experience), with a minimum of 10 years Regulatory Affairs experience in drug development and product registration activities.
- Experience with regulatory processes, including meeting request procedures, preparation and submission of briefing documents, annual reports, safety reports and other updates
- Deep understanding and knowledge of regulatory submission requirements such as IND, IDE, IMPD, CTA, CTN, NDA, MAA, JNDA and combinations product application and also demonstrated experience interacting with multiple divisions within the FDA
- Full functional knowledge of regulatory requirements (Directives, Regulations, and Guidance) pertaining to the development in nonclinical, clinical, manufacturing, process validation, analytical operations, compliance and registration of drug products in multiple ICH regions
- Knowledge of international regulatory activities such as European EMA scientific advice, health technology assessments and Japan PMDA consultation processes at all stages of pharmaceutical drug development
- Successful submission, approval, and post-approval management of product registrations (such as NDA, MAA, JNDA etc.) in multiple global regions. Recent experience in marketing submissions is a must • A strong understanding of US, EU and Asia (at a minimum) and other international pharmaceutical guidelines and regulations is required • A thorough knowledge and understanding of pharmaceutical manufacturing and regulatory requirements for drug approval is necessary • Electronic regulatory submission proficiency with good computer skills and

knowledge is essential for the compilation and filing of regulatory documentation in eCTD and also rolling submissions

- Deep knowledge and understanding of drug development process, regulatory requirements and experience in multiple therapeutic areas; such as ophthalmology, nephrology and hematology and understanding of
- Dynamic individual with demonstrated strategic thinking ability, planning and knowledgeable in orphan drug, breakthrough therapies, fast track, accelerated approval, priority review and PRIME is highly desirable
- Ability to set priorities, work independently and deliver results in a timely manner with excellent problem-solving skills and ability to make difficult judgment calls within sphere of responsibility
- Experienced in providing regulatory expertise during due diligence and in support of new projects

Skills, Knowledge & Abilities:

- Must be creative and an analytical problem solver, who acts decisively, yet communicates the risks and benefits associated with all potential solutions so that informed business decisions can be made
- Expresses ideas and information effectively and constructively with a strong planning and organizational skills to ensure that timelines are met or exceeded
- A competent, collaborative, productive and well organized individual who can communicate, influence, plan and implement effective processes to meet deadlines, demonstrates effective use of time, and can handle multiple assignments simultaneously
- A strategic thinker capable of conceptually and systematically achieve set regulatory goals with excellent ability to communicate both written and verbal and also to present information effectively and efficiently to all levels of audiences
- Offers strategic regulatory consultancy to senior management, identifies and responds appropriately to regulatory issues and challenges and providing adequate and innovative solutions.to resolve the issues
- Lead and support Business Development opportunities by providing regulatory input on assigned RFPs, RFIs and BDMs, including representing GRA at internal and external BD meetings.
- Passionate about growing a strong and productive global regulatory organization
- Proven leadership, creative thinker, motivational leader and experienced in program management
- Strong team member and collaborative team player who proactively make changes as needed to support changing priorities

Apellis is…

A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

Visit **http://apellis.com/about.html** to learn more.

EEO Statement:

Apellis is an equal opportunity employer and complies with all applicable federal, state and local fair employment practices laws. Apellis strictly prohibits and does not tolerate discrimination against employees, applicants or any other covered persons because of race, color, religion, creed, national origin or ancestry, ethnicity, sex (including pregnancy), gender (including gender nonconformity and status as a transgender or transsexual individual), age, physical or mental disability, citizenship, past, current or prospective service in the uniformed services, genetic information, marital status, AIDS/HIV status, smoker/nonsmoker, and occupational pneumocononiosis or any other characteristic protected under applicable federal, state or local law.