Manager, Regulatory Operations, Waltham, Massachusetts

Responsibilities:

The Manager of Regulatory Operations will be responsible for managing the efforts for publishing and filing regulatory submissions as well as the implementation of systems and procedures used to support regulatory submission activities. This will include paper and electronic submissions, eCTD production, document publishing and document management. He/She will be responsible for planning and scheduling submission timelines and tracking project deliverables to allow timely completion of projects. The Manager will be knowledgeable in CTD/eCTD structure and requirements and have a solid understanding of submission requirements for US and international regulatory authorities such as IND, CTA, IMPD, NDA, NDS, MAA, DSUR, PSUR, etc.Responsible for document management and retention.

- You will be the point person for the planning and scheduling project timelines and tracking project deliverables using appropriate tools control to allow timely completion of specific projects ensuring deadlines are met to accomplish company strategy, commitments, and goals.
- Oversee global publishing and submission process for domestic and international regulatory bodies.
- Manage the process from inception to approval with a focus on delivery with excellence while maintaining quality and compliance.
- Work with vendors/contractors for electronic document capture, generation, manipulation, scanning and oversee compliant archiving of all regulatory documents with access in place.
- Work to create and maintain Regulatory Timelines that can be referenced by Team members for all projects.
- Publishing paper (when required) and electronic submissions to regulatory agencies.
- Manage vendor relationship, as needed, related to regulatory operations activities.
- Represent Regulatory Operations on assigned project teams to support product submissions and scheduling to ensure efficient communication and coordination for timely regulatory submissions.
- Help develop and implement system and process improvements to support greater efficiency in regulatory operations that enhance submission standards, working practices, and documentation quality controls.
- Conduct cross functional training on submission standards, procedures and archiving standards whenever needed.
- Maintaining awareness and continually expanding knowledge of regulatory operations practices and support worldwide submission.
- Responsible for regulatory submission process improvements and establishing repeatable processes utilizing key technologies.
- Advise and provide leadership in operational functions and managing global regulatory submission and also oversees the strategic implementation of outsourcing services
- Maintain a world-class regulatory operation system and standards including publishing and archiving.

- Interface regularly with Regulatory Leads to maintain an overview of upcoming submissions for all products and, when necessary, establish prioritization between the different products under the direction of the VP Global Regulatory Affairs and Quality Assurance
- Accountable for the overall planning and management of Regulatory resources to support global submissions (IND, NDA, CTA, MAA, drug listing and maintenance activities)
- Responsible for managing the logistics, preparation, delivery and archiving of regulatory submissions in accordance with Regulatory Agency requirements, company standards, and timelines.
- Implement a submission process to support product submissions, maintenance and annual reporting for company products.
- Develop and provide in-house training on Regulatory and submission that includes authoring templates, style guide formatting requirements, processes and tools critical to compiling all submission types
- Implement the use of authoring software/tools (templates) that are compatible with vendor Regulatory submission publishing system.
- Maintains effective relationships with external publishing vendors/contractors to help manage the Regulatory submission workload.
- Manage, support and develop Regulatory Operation and secure resources to support the company's goals and objectives
- Coordinate validation of all electronic Regulatory operations systems (e.g. Part 11 compliance and GAMP 5).
- Publishing & Submissions:
    - Experience with paper submissions and conversion to electronic formats
    - Knowledge/Experience with transmission of documents to FDA via our Electronic Submissions Gateway (ESG)
    - Expertise in electronic publishing and submissions of guidance-compliant eCTD structure US and ex-US
    - Maintenance of applications throughout the eCTD lifecycle.
    - Ability to transition existing paper and NeeS (non-eCTD electronic submissions) applications to eCTD format.
    - Experience in publishing and compilation of eCTD submissions for US filings is required.
    - Strong knowledge of US and other major global (ICH, EU, Asian) regulatory requirements and operations experience with proven hands-on knowledge of pharmaceutical submission requirements for global filings.
    - Strong knowledge of Microsoft Office suite, Adobe Acrobat, Adobe Plug-Ins, electronic document management systems, eCTD publishing tools, eCTD validation and viewing tools.
- Experience working with contractor/vendor services to enhance, streamline and expedite the application process in compliance with applicable regulatory requirements.
- Ability to build and manage relationships with business partners.
- Ability to multi-task in a very fast-paced environment, manage changing departmental priorities and timelines as well as follow projects through to completion.
- Additional duties and responsibilities as required

Qualifications:

- BA/BS degree or equivalent experience.
- At least 4-5 years of Regulatory Operations experience with 6 or more years of total biotech/pharmaceutical or related industry experience preferred.
- Experience compiling electronic submissions and electronic publishing of submissions in eCTD format required.
- Experience managing internal personnel and external vendors
- Demonstrated skills managing project timelines and organizing resources
- Extensive experience using electronic document management systems

Skills, Knowledge & Abilities:

- Strong computer skills, project management skills, and a strong attention to detail, and the ability to manage multiple tasks
- Strong communication skills (both written and oral)

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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.

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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.