Regulatory Operations Submissions Specialist

Reports to: Senior Manager, Regulatory Operations

Classification: Exempt

Summary:
Responsible for the preparation, quality check and delivery of regulatory submissions and associated documentation in accordance with FDA requirements. Work closely with regulatory project leads to coordinate timelines, determine specific submission needs and make necessary revisions throughout the review process. Plays a crucial role in representing the Regulatory Operations group in publishing pivotal research documentation, and its timely delivery. The individual may also support the implementation of new systems and processes. Required to be the expert regarding the resolution of complex issues for all submission types.

Essential Functions and Job Responsibilities:

- Create, assemble and publish major and routine submissions in eCTD format per regulatory requirements, including NDAs/BLAs, INDs, annual reports, supplements, amendments, etc.
- Serve as the coordinator for internal publishing activities, interacting with project teams to assist with timelines and deliverables related to submission documents and projects
- Interface with project managers and medical writers to discuss submission preparation and provide regular updates regarding deliverables
- Proactively escalates publishing concerns, risks and issues that may delay/impact the submission and presents risk mitigation for publishing strategy
- Create submission planners for major submissions and per submission type
- Maintain working knowledge of regulations governing the content and formatting of submission documents, as required by the FDA, ICH, and other regulatory bodies
- Perform quality control review tasks and administrative duties as requested
- Serve as the internal subject matter expert for training and support on publishing and formatting processes
- Assist with standard operating procedures (SOP) and working instruction (WI) creation, update, and maintenance
- Perform additional Regulatory Affairs duties as requested

Minimum Qualifications:

- Bachelor's degree or equivalent education and at least 5 years of relevant experience in major and routine submissions to the FDA and/or other health authorities required
- Experience in preparing INDs, NDAs, BLAs
- Excellent skills in use of submission publishing tools and/or document management systems
- Proficient in Microsoft Word, EndNote, Adobe Acrobat, Acrobat Plug-ins, Document Management Systems, Excel, StartingPoint templates
- Excellent writing skills (e.g., English usage), a keen attention to detail, and strong verbal and interpersonal communication skills
- Demonstrate ability to manage priorities, multi-task and follow projects through to completion
- Ability to work autonomously under limited direction