Job Description Template

Position:	**Regulatory affairs Operations Manager/ Associate Director**
Department:	Regulatory Affairs

Job Description:

The Submission Manager drives the execution of the Global Submission Plan through collaborating with team members and vendors.

This role is a manager level role reporting into Vice President, Regulatory Affairs and has direct interactions with the Management Team, Vendors.

Duties and Responsibilities:

- focus on document formatting, word processing activities, e-submission and/or non-electronic submissions, as well as archival and record management support.
    - Familiarity with the structure of global regulatory dossiers; experience with eCTD and eCopy submissions
    - Experience with EDMS systems
    - compilation and maintenance of regulatory submissions, for various types of health authority applications (NDA, INDs, IDEs, PMAs, 510(k)s, Ad & Promo, etc.) in electronic and non-electronic mode.
    - Promotes the use of Document Management and Archival systems and standard document authoring and publishing processes, partnering with supplier groups as necessary in order to produce timely delivery of submission/archive ready components.
    - Actively participate in the definition, investigation and implementation of national, regional and global process efficiencies for paper and electronic submission execution, including the evaluation of current processes
- Ability to lead multi-functional submission teams and track progress of dossier components to ensure timely execution of submissions to Health Authorities
    - interact with responsible parties to aid in ensuring that components are received in a timely manner and provide direction to assure quality results are produced.
    - Partnering with product teams and/or third-party partners, the incumbent will be responsible for project management of activities, in support of regional and national regulatory submissions component build and delivery
    - Ongoing liaison with Project Team and country representatives to ensure paper and electronic submission requirements, translation requirements and timelines are

mutually understood and in line with corporate standards and deadlines for dossier delivery to regional and national markets

- assure regulatory guidelines are followed for electronic format, and review both submission ready documents and dossiers for compliance to these guidelines. (e.g. US export waivers, translation document management, maintenance of US PDUFA products/establishment lists, etc
- demonstrates a strong working knowledge of global regulatory practices and requirements and supports liaisons, CMC, safety, and other regulatory functions as appropriate.

Escalates, informs, and resolves any issues that may impact submission builds or the logistics of global submission delivery to regional partners or Health Authorities

Qualifications:

- BA/BS in a science/technology field with 5 years of relevant regulatory/submissions experience. B. S./B. Sc is in Pharmacy, Life Sciences, Business or Information Technology (desirable)
- Proven technical aptitude and ability to quickly learn and use new software, regulations and quality standards
- Technically savvy
- Must exhibit strong attention to detail, have good organization, communication, and collaboration skills, and seamless multi-tasking abilities to be able to work simultaneously on multiple projects, Flexibility, proactive, demonstrated accountability for deliverables, and proven ability to work in a fast-paced team environment or independently is expected
- Excellent word processing and computer skills
- Experience with E-submission software (Liquent Insight Publisher); Adobe Professional, CSC Toolbox, Microsoft Office Programs (e.g., Word, Outlook, PowerPoint, etc

Competencies:

- Strong leadership skills, with demonstrated capabilities to be agile and nimble in a start-up organization
- Strong communication skills across all levels of the organization.
- Demonstrated strong interpersonal skills, a flexible, collaborative and team-oriented approach to problem solving, and an ability to work in a fast-paced, rapidly changing environment.

Revision History

Approver Signature:

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Name, Title
Department

Date