Corporate	Master Job Description
	Revision:

Department	Regulatory Affairs		
Job Title	Senior Manager Regulatory Affairs	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Chief Executive Officer		

1. Role Purpose:

(Provide a brief summary of the primary purpose of this role)

The Senior Manager of Regulatory Affairs is responsible for regulatory submissions and maintaining submission information in a proper RA systems. The incumbent works cross-functionally with internal departments and external resources on source documents and Regulatory related issues, ensuring those are in compliance with FDA regulations and company SOPs. The incumbent is also responsible for preparation of labeling and artwork, eCTD compilation and submission for ANDAs and NDAs registration and maintenance.

2. Key Duties & Responsibilities:

(Briefly describe the essential activities that are performed by this role including key duties/responsibilities. Each statement should start with a verb. Additionally, indicate how frequently it is performed)

- Knowledge/Experience of Chemistry, Manufacturing and Control sections of original Abbreviated New Drug Applications (ANDA), amendments, supplements, and annual reports.
- Knowledge/Experience of Chemistry, Manufacturing and Control sections of New Drug Applications (NDA), amendments, supplements, and annual reports.
- Review of Drug Master Files (DMF), amendments, supplements and annual reports.
- Strong knowledge of United States of Pharmacopoeia.
- Comply to FDA guidelines/Company Policies of Data Integrity
- Expert knowledge of Title 21 of Code of Federal Regulations, various US FDA guidance and ICH guidelines
- Oversee the interviewing, hiring, training, and development of all department personnel, ensuring employees can function effectively in a team environment.
- Comply with FDA guidelines/Company Policies of Data Integrity.
- Other duties as assigned.

- **Regulatory Submissions:**
  - Work cross-functionally with internal departments and external resources (e.g., CROs, CMOs) to ensure that source documents are received in a timely manner for submissions.
  - Prepares original ANDAs and NDAs, amendments ensuring these are in compliance with applicable FDA regulations.
  - Performs documents formatting and publishing to ensure that submission documents adhere to FDA eCTD requirements and company SOPs.

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- Has responsibility for archiving of all original submissions in a secure system and maintains and keeps an up-to-date record of all correspondence with FDA.

- **Labeling and Artwork:**
  - Work cross-functionally with internal departments and external resources to ensure that labeling and artwork are received, reviewed and approved in a timely manner for submissions.
  - Prepares contents of labeling for new registration and/or revised labeling of drug products in accordance with RLD and applicable FDA regulations (e.g., 21 CFR 201 and 208).
  - Proofreads, reviews and approves labeling printer proofs to ensure accuracy of contents, completeness and integrity.
  - Monitors RLD labeling updates and initiates change requests, if necessary, for labeling of all new registration and marketed products in accordance with RLD.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

To manage and oversee the regulatory affairs department.

4. Education & Experience:

(Describe the education required for this role, including specifications, if any. If equivalent experience or knowledge can be substituted for the educational requirements, A combination of Education and experience shall be taken into account.)

Education Requirement	Specialization (If any)
BS in Chemistry or related science field preferred	*N/A*
N/A	*N/A*

Experience Requirement

(Describe the experience required for this role. Identify the type of experience, number of years, and any additional comments on the experience and education requirements for the role. Also, include any geography specific requirement that differs from the experience.)

N/A	
Number of Years (Minimum to Maximum)	*N/A*

5. Technical competencies/ Certifications/ Licenses:

(Briefly describe the required competencies such as, skill, ability, knowledge an individual must possess to perform the role. Also, identify any certification or licenses required to perform the role.)

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Technical competencies	• Proficient with use of technologies (e.g. Adobe Acrobat, ESG, XML, SPL) and eCTD publishing tools • Strong working experience in ANDA, NDA eCTD submissions. • Working knowledge of FDA regulations (e.g., 21 CFR 314.50 and 314.94 and 21 CFR 201 and 208) and applicable FDA guidance. • Must demonstrate strong leadership skills • Possess strong attention to details. Excellent multi-tasking skills and ability to manage multiple competing projects while meeting project timelines • Performs other duties as assigned. • Complies with company polices and SOPs. • Minimum of 10 years of experience in the Pharmaceutical industry preferred • Good written and oral communication skills • Experience in statistical analysis, process capability reviews with software • Ability to act independently • Excellent interpersonal, verbal and written communication skills
Certifications	*N/A*
Licenses	*N/A*
Other	*N/A*

6. Physical demand and Work environment:

(Provide details regarding the physical demands and work environment that are essential to the role)

a. Physical demands:

While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

b. Work environment:

N/A