Corporate	Master Job Description
	Revision:

Department	Regulatory Affairs		
Job Title	Regulatory Associate	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To			

1. Role Purpose:

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

Primary responsibility is writing regulatory submissions by successfully coordinating with the Manager for priorities; while maintaining compliance with cGMP requirements, FDA, OSHA, EPA, and DEA.

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)

- Interact with cross functional teams for procurement of documentation required for regulatory submissions.
- Review technical documents for accuracy and with supervision, determines acceptability for use in regulatory submissions (i.e. ANDA and NDA)
- Create documents in accordance with eCTD specifications.
- Update and maintain the internal database as needed
- Comply with FDA guidelines/Company Policies of Data Integrity
- Other duties as required or delegated

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

N/A

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)
Bachelor's Degree in Pharmacy, Chemistry or Scientific Discipline preferred	*N/A*
N/A	*N/A*

Experience Requirement

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(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.)

Technical competencies	• At least 1 year experience with technical writing preferred • Minimum 3 years Pharma experience preferred • Proficient with Adobe PDF, Illustrator/In Design, Microsoft Office and advanced computer skills • Continuous working knowledge of applicable FDA/ICH/DEA regulations • Continuous working knowledge of applicable cGMP guidelines
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