

Corporate	Master Job Description		
	Revision:		

Department	Technical Services		
Job Title	Technical Writer	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Technical Services Supervisor		

1. Role Purpose:

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

Primary responsibility is the preparation of technical documents, including Standard Operating Procedures, Manufacturing Batch Records, Protocols, and Reports. Additional responsibilities may include investigating and documenting all deviations and customer related complaints related to the Manufacturing, Packaging and Shipping/Receiving departments by reviewing all related documents, and interviewing relevant personnel so as to identify the root cause and corrective actions required. Also, to change or correct any related documents pertinent to the conclusion of the investigation (i.e., SOP's) 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)

- Prepare and review Master production and packaging batch records
- Prepare and review Validation Protocols and reports
- Prepare Quality Event Records (including deviation, incident reports, planned deviation and product complaint investigations)
- Prepare and Review Risk Assessments, CAPAs, Change Control documents and Standard Operating Procedures (SOPs)
- Handles and completes special projects as required
- Other duties as assigned 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)
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• B.S. or higher degree from an accredited college/university in a scientific discipline or English 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
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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	<ul style="list-style-type: none"> • Practical working knowledge of Pharmaceutical Manufacturing Operations preferred • Excellent English writing, spelling, punctuation, and grammar skills • Ability to interpret complex data and draw valid conclusions • Proficient in the use of spreadsheets, databases, presentation, and word processing software. Basic Microsoft Office proficiency is expected. • Strong interpersonal skills and the ability to effectively work and communicate with cross-functional teams • Strong organizational and multi-tasking abilities • Self-motivated, work well independently and as a team player and re-prioritize workload as required • Continuous working knowledge of applicable cGMP guidelines and DEA regulations
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

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abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

b. Work environment:

N/A