

Corporate	Master Job Description		
	Revision:		

Department	Technical Services		
Job Title	Technical Services Associate	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Senior Manager of Technical Services		

1. Role Purpose:

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

This individual is responsible for providing technical and proposal writing support to the Technical Services division. Additionally, the position will also assist with development and delivery of process records for production. Additionally, writing investigations and Standard Operating Procedures, Technical Transfer Documents, and Validation reports. Execute all functions in accordance with current FDA regulations, ICH guidelines, USP methodologies, cGMPs and SOPs.

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)

- Develop, write and review of technical documentation which includes manufacturing/packaging batch records.
- Ability to learn new techniques, perform multiple tasks simultaneously, keep accurate records, follow instructions, and comply with company policies.
- Manage the review, tracking, GMP compliance and approval of Change Controls for Production Processes, Facilities and Equipment.
- Develops, writes and reviews/updates SOPs.
- Prepares various summary forms for Pharmaceuticals related projects as well as graphs, charts and statistical analysis for establishing product specifications.
- Designs, develops and implements databases to track key project deliverables and resource allocation within Pharmaceuticals and updates on an ongoing basis.
- Provide investigation expertise and technical writing expertise to perform and document process Deviations and Events.
- Implements Change Control management in production and engineering.
- Review and approve documentation associated with cGMP Compliance. Assess and document product quality impact.
- Assist regulatory to provide technical documentation for submission.
- Assists with the development of departmental project timelines and project plans.
- Other duties as delegated.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

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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 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.)

Technical competencies	<ul style="list-style-type: none"> • Preparation and approval of Standard Operating Procedures. • Preparation and review of Quality Risk Management for process, area and equipment. • Assist with quality improvement initiatives as needed. • Assist with development/writing of SOPs or other quality documents and/or reports as needed. • Complies with company policies and SOPs. • Good written and oral communication skills. • Experience in statistical analysis, process capability reviews with software. • Ability to act independently. • Strong organization skills, attention to detail, and the ability to work in a team, fast paced environment. • Excellent interpersonal, verbal and written communication skills • Recommended to have a BS in Science or related science field.
Certifications	N/A

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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