Corporate	Master Job Description
	Revision:

Department	Technical Services		
Job Title	Group Leader	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)

The Group Lead of Technical Services is responsible for department activities in providing technical and proposal writing for the organization. This includes writing Standard Operating Procedures, Technical Transfer Documents, Validation Reports, Manufacturing Batch Records, Protocols, Pre-Development and Pharmaceutical Development Reports, investigations and other various documents. Additionally, the position will assist with the development and delivery of process records for production.

Technical Services role requires preparation of process validation protocols, process validation reports, and commercial batch records preparation.

Manages documentation compliance and change control for R&D. Execute all functions in accordance with current FDA regulations, ICH guide lines, USP methodologies, cGMPs and SOPs. Must perform all work independently with minimal supervision.

Person requires training of staff on technical documents writing in accordance with current FDA regulations. Guides the technical services staff meeting to Organizational Requirements.

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/update R&D SOPs, and technical documentation which includes Manufacturing/Packaging batch records.
- Writes Development protocols and reports for R&D.
- Prepares documentation for submission of new ANDA filings.
- Assists in the response to FDA deficiency letters for ANDA filings for answering Pharmaceutics related findings.
- Prepares various summary forms for Pharmaceutics 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 Pharmaceutics and updates on an on-going basis.

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- Prepares presentations to share project status updates.
- Implements Document Management.
- Handles research and writing projects.
- Implements Change Control management.
- Comply with FDA guidelines/Company Policies of Data Integrity.
- Ensures Technical Services team follows current SOP's
- 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.
- 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)

Train and mentor Technical Services Staff

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)
B.S in Chemistry or related discipline general pharmaceutical 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:

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(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	• cGMPs, Food and Drug Administration and other regulatory compliance requirements preferred. • Pharmaceutical principles, practices and applications preferred. • Documentation and technical writing principles and practices preferred. • English usage, spelling, grammar and punctuation. • Related business, scientific and personal computer hardware and software applications. • Strong organization skills, attention to detail, and the ability to work in a team and fast paced environment. • Minimum 3 years' experience working in a pharmaceutical company preparing technical documents preferred • 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. • Ability to communicate clearly and concisely using both written and verbal communication. • 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:

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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