Corporate	Master Job Description
	Revision:

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

1. Role Purpose:

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

Primary responsibility is to complete documentation and analytical testing of raw materials, in-process materials, stability samples, finished products and product development in a timely manner, 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)

- Follow cGMP (current Good Manufacturing Practices), GLP (Good Laboratory Practices), 21CFR211.22, 21CFR211.28, 21CFR211.170 and ALCOA principals.
- Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations.
- Follow all DEA (Drug Enforcement Agency) regulations per laboratory SOPs.
- Perform analytical testing of raw materials, in-process materials, stability samples, finished products and product development products using different analytical techniques in compliance with written, approved methods.
- Document all performed analysis as per cGMP, USFDA and 21CFR211.194 guidelines. Maintain laboratory records including notebooks, logs, and other pertinent documentation in compliance with cGMP, SOPs, and good laboratory documentation guidelines.
- Operate, Calibrate, Qualify, or perform Preventive maintenance and routine trouble shooting on analytical instruments such as UPLCs, HPLCs, GCs, AAS, UV/Vis spectrophotometers, Dissolution apparatus, Laser Diffraction Particle Size analyzers, etc. as assigned (if trained).
- Ensure all instruments are qualified, and calibrated before each use.
- Ensure all instruments are maintained, cleaned and used appropriately.
- Evaluate existing, as well as verify and validate new analytical methods of drug products and drug substance as per FDA, USP and ICH guidelines.
- Research and gather information in a timely manner.
- Prepare, label, organize and maintain files.

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- 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
- Research and gather regulatory/scientific information/data as instructed and assist senior chemists/scientists in evaluating, verifying and validating new analytical methods for drug products and drug substances as per FDA, USP and ICH guidelines;
- Follow all SOPs.
- Comply with FDA guidelines/Company Policies of Data Integrity
- 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)
BS 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.)

Technical competencies	• Working knowledge of HPLC, UPLC, GC Dissolution, AA, UV spectrophotometers • Aptitude for application of analytical methods

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	• Skilled in laboratory techniques • Good verbal and written English • Excellent interpersonal and 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