

Corporate	Master Job Description		
	Revision:		

Department	Quality Assurance		
Job Title	Associate Director of Corporate Quality Assurance	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Senior Director of Corporate Quality Assurance		

1. Role Purpose:

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

The primary responsibility of this role is to ensure the quality across all KVK Tech sites and entities. This includes collaborating with Quality and Production Personnel for priorities; ensuring product is produced in compliance with cGMP, FDA, OSHA, EPA, and DEA 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)

- Align with and meet Company goals and deadlines
- Oversee regulatory filing documents with a focus on ANDA batch records and batches.
- Supports regulatory filings and associated data collection
- Reviews ANDA batch records
- Collaborates and supports R&D ANDA related activities, including process validation
- Reviews and approves process validation, cleaning and sterilization validation, and equipment qualification documents
- Ensures change control documentation is comprehensive from the validation perspective
- Reviews and approves Stability Protocols and Reports.
- Reviews and approves SOP's and Master Batch Production and Packaging Records.
- Support the Site Quality Metrics program.
- Ensure that commitments to Regulatory Agencies are met and maintained
- Handles and completes special projects as required
- Annual Product Reviews
- Lead, or participate in Continuous Improvement projects.
- Review and approve investigations pertaining to process, equipment, or cleaning issues
- Oversee and support the Annual Stability program.

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- Ensure production batch records align with the parameters from ANDA batch production
- Create and manage administrative and GMP documents (electronic/hard copy) as needed
- Oversee the interviewing, hiring, training, and development of all department personnel, ensuring employees can function effectively in a team environment
- Comply with FDA Guidelines/Company Policies of Data Integrity
- Adhere to cGMP policies, procedures, work instructions, and training.
- Develop and maintain good working relationships across all levels in the organization.
- Perform other work-related duties as assigned.
- Continuous working knowledge of applicable cGMP guidelines
- Demonstrates a high level of confidence, integrity and motivation
- A collaborative mindset is required
- Knowledgeable in all aspects of 21 CFR 210 and 211 regulations
- Understanding of Laboratory finished product testing and requirements
- Handles confidential and non-routine information with poise, tact, and diplomacy
- Flexible and responsive with an upbeat attitude.
- Outstanding administrative and organization skills; is detail-oriented self-starter; is able to independently prioritize and multitask; follows through consistently; demonstrates ownership through responsibility and accountability for end product; is proactive and persistent in job efforts; does not get frustrated with time limitations or high-pressure situations; works productively when under pressure
- Anticipates and meets the needs of executives, teams and administrative colleagues
- Ability to work effectively in a fast paced, timeline-driven, extremely high-expectation environment; is flexible to occasionally work overtime on short notice
- Takes initiative and exhibits resourcefulness in problem solving; experienced in working in a collaborative team environment
- Maintains confidentiality at all times and exercises solid, dependable judgment and discretion
- Displays effective interpersonal and communication skills, both oral and written (timely, clear, succinct); constructively delivers and receives feedback
- Experience with FMEA and Risk analysis approaches.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

- This position will require interviewing, hiring, training, and development of department personnel.
- This position will have direct report(s), requiring oversight, development and performance review activities.

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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)
BS/MS 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	<ul style="list-style-type: none"> • Efficiently type, format, edit and proofread formal documents and correspondence • Strong root cause analysis and technical writing skills • Ability to address issues • Strong organizational and multi-tasking abilities • Proficient in MS Word, Excel, MS PowerPoint, and Electronic Quality Systems. • Working knowledge of applicable DEA regulations is preferred • Familiar with aseptic technique
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