KVK Tech	Master Job Description
	Revision:

Department	Quality Control		
Job Title	Group Leader of Investigator	FLSA Status	Exempt
Role	Metrology Analyst		
Sub Role (If any)	N/A		
Reports To	QC Manager of Investigations		

1. Role Purpose:

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

Primary Role Purpose:
Investigate QC Laboratory incidents, Out of Trend and Out of Specification results in support of QC Laboratory commercial and Stability testing programs and in compliance with cGMPs and approved procedures. Provide expertise to troubleshoot, perform minor repairs, maintenance and calibrations.

Secondary Role Purpose:
Lead qualifications of instruments and calibrations.

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)

Primary Key Duties & Responsibilities:

- Conduct timely and thorough laboratory investigations, ensuring compliance with departmental SOPs and FDA guidelines
- Autor and review investigations, proposed CAPAs, investigational protocols and reports ensuring conclusions and actions are appropriate for the identified root cause.
- Conduct investigational and/or remedial testing as required
- Guide assigned personnel and/or remedial testing as required
- Guide assigned personnel in conducting through, compliant laboratory investigations
- Provide weekly status and summaries of lab incidents and investigations to the investigational Review Board when requested
- Follow and enforce compliance with cGMP, cGLP, 21CFR211.22, 21CFR211.28 and 21CFR211.170 regulations
- Ensure all QC laboratory Investigation records and documentation are maintained as per cGMP and 21CFR211.194 guidelines. Ensure Data Integrity
- Follow and enforce all DEA guidelines
- Author and review investigational, analytical, cleaning validation protocols and reports, SOPs, CAPAs and other documents as assigned

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- Support review of analytical methods and specification revisions
- Responsible for improving training in analytical techniques, documentation and regulations especial those connected with laboratory investigations
- Follow the OSHA and EPA safety regulations
- Ensures that all laboratory team leaders, chemists, staff members and visitors adhere to all safety procedures and identifying/communicating the necessary adjustments to address potential safety concerns. The manager will also ensure the team leaders are enforcing the proper wearing of PPE.
- Work with Microsoft Excel, Word and possibly PowerPoint
- Handle and complete special projects as required
- Create and manage administrative documents as needed
- Other duties as assigned or delegated

Secondary Key Duties & Responsibilities:

- System level impact analysis
- Preparation of URS for new equipment's
- Risk assessment and validation plan
- Perform IQ, OQ and PQ for analytical equipment's
- Preparation of SOP's
- Perform calibrations for analytical equipment's.
- Maintain master calibration schedules
- Troubleshoots, maintains and calibrates lab equipment required for analytical analysis to support analytical release, research, or process control.
- Provide technical/mechanical expertise to bring current procedures up-to-date and into compliance.
- Provide training to other analysts.
- Day to day activities will include walking down lab service equipment, interviewing subject matter experts, and writing/revising procedures.
- Follows approved standard operating procedures, standards and guidelines.
- Interface with internal and external customer departments during all phases of documentation development.
- Other duties as assigned.
- Experience working in a pharmaceutical or other regulated industry.
- Computer literacy, especially with Microsoft Word.
- Written and oral communication skills.
- Experience writing operational and program level procedures/work instructions.
- Capable of observing design and operation of equipment or processes and then organizing that information into written procedures.

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- Demonstrated ability to work with multiple disciplines.
- Must be a team player and embrace the culture of the compliance and safety.
- Experience with CAPA and performing incident investigations (deviations, root cause analysis).
- Carries out duties in compliance with all state and federal regulations and guidelines including FDA, OSHA, EPA, and DEA.
- Remains current in profession and industry trends.
- Review and approve the sample sequence.
- Perform investigations.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

Assist QC Investigation Manager.

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 degree in Chemistry or related 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	**Primary Technical Competencies:** • Experience in GMP Quality Control Laboratories • Proven knowledge in QC/Analytical Laboratory Instrumentation and Raw Material (API's Excipients, Packaging components) Testing

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	• Minimum 5 years of experience in the pharmaceutical industry preferred • Working knowledge of HPLC, UPLC, GC Dissolution, AA, UV spectrophotometer and other instrumental and wet chemistry techniques • Aptitude for application of analytical methods • Knowledge of USFDA, ICH, cGMP, cGLP, Safety guidelines • Critical thinking skills • Good verbal and written English • Excellent interpersonal, verbal and written communication skills • Effectively performs a variety of duties, on schedule, with accuracy and competency. **Secondary Technical Competencies:** • Naturally positive, upbeat attitude • Proficient use of basic analytical instrumentation • Critical Data Analysis Skills • Thorough time management skills • Neat and precise penmanship • Organized • Demonstrates a high level of confidence, integrity and motivation • Handles confidential and non-routine information with poise, tact, and diplomacy • 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 • Professional and tactful • Strong typing and proofreading skills; and the ability to produce typed documents quickly and accurately • Demonstrated proficiency in MS Word and MS PowerPoint. Intermediate skills in MS Outlook and

	MS Excel; and the ability to learn other applications as required • Demonstrates effective interpersonal skills; exhibits a positive attitude; is able to build relationships within the lab 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 communication skills, both oral and written (timely, clear, succinct); constructively delivers and receives feedback
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