KVK Tech	Personnel Job Description

1. Personnel Details:

First Name		Middle Initial		Last Name	
Hire Date		Department	Quality Control		
Location	110 Terry, 100 Campus	Job Title	Director	FLSA Status:	Exempt
Role	N/A				
Sub role (If any)	N/A				
Reports To	Senior Director of Corporate Quality Control				

2. Role Purpose:

Quality Control Director is expected to lead a Quality Control Chemistry team to support commercial manufacturing operations and Stability testing program.

3. Key Duties & Responsibilities:

- Comply with FDA guidelines/Company Policies for cGMPs and Data Integrity
  - Implement an on-going process to assess and ensure compliance/inspection readiness through Regular internal audits/assessments and Analyst training/awareness.
  - Maintain compliance with current compendia (USP)
- Oversee Quality Control Operations
  - Analytical activities
    - routine commercial product testing, submission batch and process validation testing,
    - routine raw material testing for commercial products
    - Testing, Method Validations and Transfers for new raw materials,
    - Stability testing,
    - Cleaning Validations,
  - Managing Change Control for QC documents
    - Review and approval of Standard Operating Procedures, and test methods.
  - Calibration and Maintenance of Laboratory Instruments
  - Review and approve Laboratory Investigations and assist in Problem Solving
  - Review and approval of Process Validation, Cleaning Validation and Stability protocols.
  - Review and approval of Annual Product Review reports
  - Oversee the interviewing, hiring, training, and development of all department personnel, ensuring employees can function effectively in a team environment.
- Drive continuous improvement efforts in QC Laboratories to include:
  - Develop and mentor staff
  - Establish a holistic and robust analyst training program,
  - Trend, analyze and remediate process/product deviations
  - Implement CAPA plans and drive completion in a timely manner.
  - Establish meaningful metrics and processes to drive quality and efficiency

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- Quality Systems enhancement
- Direct and coordinate QC Quality Plan initiatives to include:
  - Method enhancement remediation
  - Product /Process Monitoring and In-Process Controls
  - E-Systems enhancement/implementation

4. Typical Supervisory Responsibility:

Oversee entire quality control department.

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	• Experience in GMP Quality Control Laboratory Management. • Proven knowledge in QC/Analytical Laboratory Instrumentation and Raw Material (API's, Excipients, Packaging components) Testing. • Minimum of 10 years of experience in the Pharmaceutical industry • Working knowledge of HPLC, UPLC, GC Dissolution, AA, UV spectrophotometer • Aptitude for application of analytical methods • Knowledge of USFDA, ICH, cGMP, cGLP, Safety guidelines • Critical thinking skills • Good English • Excellent interpersonal, verbal (listening and speaking) and written communication skills • Effectively performs a variety of duties, on schedule, with accuracy and competency. • Serves as an effective member of the Quality team and may serve as a mentor to other Quality employees in the area of expertise. • Experience in statistical analysis, process capability reviews with software • Ability to act independently
Education/Certifications/Licenses/Other	• MS/PhD in Chemistry or related science field preferred

6. Physical Demand and Work Environment:

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