KVK Tech	Employee Job Description

1. Employee details:

First Name		Middle Initial		Last Name		
Hire Date		Department	QA			
Location	110 Campus 110 Terry	Job Title	QA – Deviations and Compliance		FLSA Status:	Exempt
Role	QA Deviations and Compliance					
Sub role (If any)	N/A					

2. Role Purpose:

QA– Deviations and Compliance ensures Reviews, coordinates, and assists to ensure non-conformances are adequately invested for determination of root cause and product impact per FDA regulations. In addition, ensures that corrective and preventative actions (CAPA) are identified and implemented to prevent/reduce reoccurrence. Oversee product complaint investigation process to ensure they are adequately investigated, within defined timeframes. Other deviation related activities performed by this individual will include maintaining quality databases and performing trend analyses and reporting metrics where required. This individual will also be responsible to perform review and approval of master as well as executed production/packaging records and to ensure that quality activities are executed in compliance with cGMP requirements.

3. Key Duties & Responsibilities:

- Oversee the initiation, root cause analysis and closure deviation investigations occurring in the manufacturing, packaging, facility and warehouse departments.
- Gather and analyze historical data to identify trends and root cause of manufacturing, packaging, facility and warehouse deviations.
- Manage and trend the deviation process while ensuring that a thorough investigation report is completed in a timely manner using proven root cause analysis tools.
- Monitor the deviation investigation progress and support the process to bring deviations to a closure in a timely manner.
- Chair the investigations review Board (IRB) meetings, issue minutes and follow up on corrective and preventative actions.
- Managing and handling of electronic documentation in Master Control for Market Complaint and deviation related investigations as well as CAPAs.
- Manage all CAPA commitments to ensure timely completion of the outline's tasks and effectiveness.
- Manage the Customer Complaint system for both product and adverse event complaints; ensuring investigations are performed in time and any notifications meet regulatory reporting requirements (i.e. Field Alert Reports (FARs), 3 day and 1-day alerts, etc.).

- Preparation, review and approval of departmental as well as cross functional departmental standard operating procedures.
- Review and approval of Master production and packaging records.
- Review and approval of executed production and packaging records including review of other supporting documentation to ensure that all information contained within is correct and accurate.
- Manage the collection and generation of Annual Product Reviews (APRs); ensuring the timely approval of all APR's and the continued improvement of the generation process and the effectiveness of the utilization of report contents and data.
- Act as the SME for Investigations, CAPAs and Production/Packaging record reviews.
- Coordinate and handle weekly Investigation Review Board meetings.

4. Typical Supervisory Responsibility:

Serves as an effective member of the Quality team and may serve as a mentor to other Quality employees in the area of expertise.

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	• Must be independently able to manage all aspects of conducting thorough timely investigations for identification root cause. • Capable of identifying and assigning proper corrective and preventive actions and their implementation. • Proficient with computer programs specifically electronic document management systems • Preparation, approval of Standard Operating Procedures. • Effectively performs a variety of duties, on schedule, with accuracy and competency. • Performs other duties as assigned • Complies with company policies and SOPs • 5+ years of experience in the Pharmaceutical industry • Good written and oral communication skills • Ability to act independently • Excellent interpersonal, verbal and written communication skills
Education/Certifications/Licenses/Other	• Must have a Bachelor's Degree in Biology or related science field.

6. Physical Demand and Work Environment:

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