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| **Department** | Quality Assurance |
| **Job Title** | Investigations Writer | FLSA Status | Exempt |
| **Role** | N/A |
| **Sub Role (If any)** | N/A |
| **Reports To** |  |

1. **Role Purpose:**

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

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| Primary responsibility isto investigate, document and bring to conclusion the outcome of product/processing related incidents, deviations or documentation errors reported to the site QA. The investigations assigned include manufacturing and packaging, finished product, raw materials, components, product storage/distribution and customer complaints. Coordinates the required activities with the functional areas to obtain and compile the appropriate information that can lead to finalize the investigation report. Utilizes investigative tools and techniques to identify and evaluate the cause of an event including root cause analysis, impact or risk analysis, corrective and preventative actions and monitoring effectiveness of implemented actions to comply with the FDA cGMPs investigation requirements/guidelines. Recommends, proposes and formalizes alternatives for the improvement of processes, utilities and systems. Responsible for writing and reviewing Risk Assessment Report per Q9. Responsible for writing and reviewing Protocols and Reports. |

1. **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)*

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| * Responsible for thoroughly investigating events as it relates to deviations and customer complaints communicated to or informed by QA and applying a science-based approach to accurately, correctly and timely document the final report utilizing appropriate investigation techniques and/or tools.
* Reviews and uses the established follow up mechanism to ensure that applicable investigations are initiated, timely completed, final reports issued and approved by QA.
* Evaluates and discusses the impact of the reported events to ensure that its effect on previously approved product has been considered as part of the investigation process and that actions are identified to prevent its recurrence.
* Reviews and evaluates each event under investigation against the applicable metrics defined/implemented to monitor the effectiveness of corrective and/or preventive actions and communicates results to site management on the established frequency or as agreed upon.
* Maintains an updated knowledge of the cGMP regulations and FDA Guidelines and utilizes those principles in the investigation process and final report issuance.
* Keeps abreast of the site products, quality systems, controls, projects and processes to ensure that investigations outcomes are consistent with the existing operating environment.
* Participates in the review of APR recommendations and the change proposals in order to challenge the implementation in relation to the product/system to assure that appropriate documented evidence supports the changes/recommendations and that its effect on product quality can be either anticipated or mitigated.
* Defines the investigation data needed from the applicable functional areas to prepare and revise the documents involved in the assigned investigations in order to track and ensure that these are completed on a timely basis to effect product disposition.
* Provides technical support to Area Managers and Supervisors in the GMP related aspects associated to the manufacturing/packaging/laboratory processes, e.g., investigations, complaints, deviations, CAPAs, management of changes, APRs.
* Maintains communication with QA at other KVK Tech sites and external customers/contractors as required to ensure that, as applicable, extended investigations and/or CAPAs are understood, timely completed and followed up.
* Maintains management informed of events that will impact the quality and/or timely disposition of products.
* Participates or lead Cross Functional Investigations (CFIs), as required.
* Provide training in SOPs related to the QA area to colleagues from other functional areas, as required.
* Issue investigation reports, complaints follow-up and applicable monthly monitoring progress reports for the site.
* Utilizes available methodologies or techniques and statistical analysis tools to conduct investigations.
* Coordinates training of supervisors and operators in documentation of Quality Assurance procedures to ensure compliance and adherence to GMPs and established procedures.
* Assists appointed Teams and meetings to address quality and compliance issues and makes recommendations.
* Supports other functions in the Quality organization, as necessary.
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1. **Typical Supervisory Responsibility:**

*(Identify any responsibilities the role has for supervising others)*

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| N/A |

1. **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.)*

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| **Education Requirement** | **Specialization (If any)** |
| College Bachelor's Degree in Natural Sciences, Pharmacy, or Engineering. Master degree is desirable, but not a must. | *N/A* |
| *N/A* | *N/A* |

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| **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*.)

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| *Three to five years-experience in the pharmaceutical industry preferably with supervisory experience in the manufacturing, packaging, laboratory and/or Quality Assurance areas.* |
| Number of Years (Minimum to Maximum) | *3-5* |

1. **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.)*

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| **Technical competencies** | * Strong technical writing skills
* Results oriented, self-starter and ability to question the status quo.
* Proven ability to work under pressure and availability to work at any time needed.
* Capable of managing the stress levels and assertiveness to obtain the participation of colleagues working in assigned tasks
* Effective in organizing work, working area, managing time and planning to achieve results.
* Self-motivated, creative and teamwork oriented.
* Proficient in negotiation skills and business savvy/awareness.
* Proficiency in handling concurrently and effectively multiple high-priority initiatives with evident sense of urgency and sound Quality minded approach.
* Proficient knowledge of cGMP’s and FDA regulations.
* Knowledge of computer systems GMP requirements for Part 11 compliance
* Technical knowledge in pharmaceutical manufacturing processes, technologies, process validation and processing equipment.
* Proficient in the use of Personal Computers, including knowledge of word processing, Power Point type presentations, spreadsheets, database and electronic mail applications.
* Self-motivated, creative and teamwork oriented.
* Knowledgeable and proficient in problem solving skills and statistical analysis of data as well as a high level of attention to detail.
* Ability to establish and maintain effective working relationships at all levels
* Demonstrated ability to maintain confidentiality.
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| **Certifications** | *N/A* |
| **Licenses** | *N/A* |
| **Other** | *N/A* |

1. **Physical demand and Work environment:**

*(Provide details regarding the physical demands and work environment that are essential to the role)*

* 1. 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. |

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* 1. Work environment:

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| *N/A* |