

KVK Tech	Employee Job Description
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1. Employee details:

First Name		Middle Initial		Last Name	
Hire Date		Department	CSV		
Location	110 Campus 110 Terry	Job Title	Computer System Validation	FLSA Status:	Exempt
Role	N/A				
Sub role (If any)	N/A				

2. Role Purpose:

CSV Associate will work as help desk staff for other cross functional teams as appropriate to determine and resolve problems. The CSV Associate will respond to queries, isolated problems and determine and implement solutions. Perform daily system monitoring to ensure that all computer-based system will produce information or data that meet predefined requirements. This position requires the ability to resolve end user problems quickly. You must have excellent communication skills (both verbal and written), must manage time effectively and have strong organizational skills. You must also possess the ability and judgment to escalate support requests if necessary.

3. Key Duties & Responsibilities:

- Familiarity with software development life cycle, GAMP5 approach to software implementation
- Collaborate with system owner to develop URS, Design Qualifications, Functional Requirements, Unit test scripts, UAT scripts, Validation Plans and Protocols, Validation summary report and Traceability matrix
- Develop procedures specific to GxP Application SOP's and provide SOP review for new systems.
- Perform Part 11 Assessments for new and existing computer systems
- Perform periodic reviews of validated GxP Systems
- Maintain GxP System log and update as necessary
- Participate in cross-functional project team meetings
- Execute the validation protocols, test scripts per Regulatory and GAMP guidance
- Perform Risk assessments for GxP systems
- Identify and implement opportunities for continuous improvement related to validation or other compliance practices/issues based on internal compliance issues, industry best practices as well as latest regulatory guidance's and regulatory updates
- Identify, communicate and escalate project and compliance related issues associated with their projects to project Manager/Management
- Conduct training to individuals performing various roles within validation projects

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- Review and assess the impact of new Patches to validated GxP systems and validation of new patches
- Experience in project Management practices and assessing GxP risk, functional and usage risk for any given GxP Application techniques
- Knowledge of pharmaceutical principles, practices and applications
- Demonstrates ability to perform detail-oriented work with a high degree of accuracy
- Effective time management and interpersonal skills
- Strong organizational skills, planning skills and must work effectively within teams
- Initiate and resolving any non-conformance observes during periodic reviews through change and incident management
- Participate and coordinate with CFT for new projects
- Must have sound understanding of Drug Regulations, Pharmacopeia, Regulatory Requirement, Laboratory compliance and adherence to cGMP requirements
- Other duties as assigned

4. Typical Supervisory Responsibility:

N/A

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	<ul style="list-style-type: none"> • One-year pharmaceutical industry experience preferred • Applicable knowledge of DEA regulations • Maintains a safe working environment. • Organized • Demonstrates a high level of confidence, integrity and motivation • Handles confidential and non-routine information with poise, tact, and diplomacy
Education/Certifications/Licenses/Other	<ul style="list-style-type: none"> • Associates degree in related field from an accredited college or university preferred

6. Physical Demand and Work Environment:

a. Physical demands:

While performing the duties of this job, the employee is frequently required to stand, walk, use hands to finger, handle or feel, and talk or hear. The employee must lift and/or move up to 20

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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