Corporate	Master Job Description
	Revision:

Department	Information Systems		
Job Title	Computer System Validation Associate	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Director of Information Systems and Procurement		

1. Role Purpose:

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

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.

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)

- 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
- Review and assess the impact of new Patches to validated GxP systems and validation of new patches

Corporate	Master Job Description
	Revision:

- 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

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

N/A

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)
Associates degree in related field from an accredited college or university 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	• 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
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