Job Description
Quality Assurance Associate I

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- Document control including but not limited to:
    - Formatting of documents, publishing, completing change control process
    - Document upload into training system and course creation
    - Annual document review including generation of list of documents due, issuing and tracking completion, document revision
- Issue batch record documents
- Scanning and filing of GMP records
- Metrics- tracks and trends QA Quality Management System metrics
- Reviews and provides input for Quality Management system elements including investigations and root cause analysis
- Batch record review process: assembles and reviews all manufacturing and QCL related documents and data
- Supports Internal and Client Audits
- Supports Supplier Qualification activities
- Perform shipping verifications as needed

Position Requirements

- Attention to detail and ability to consistently follow procedures
- Strong organizational skills and ability to manage multiple tasks at one time
- Demonstrated ability to work as both a team player and independently
- Excellent verbal and written communication skills; excellent interpersonal skills at all levels
- Desirable: knowledge of and ability to confirm compliance to US and EU GMP, USP, and Integrity Bio requirements
- Validation knowledge desired: software, equipment, analytical method, system Validation protocol creation, execution, and approval: Software (SQL database, Moodle platform, MS Excel, etc.), equipment, systems (facilities, etc.)
- Proficiency in MS Office
- Flexibility to travel as required for business needs (up to 10%).
- Physical Requirements
- Subject to extended periods of sitting and/or standing in an office environment
- Ability to lift 30 pounds

Education and Professional Experience

Bachelor's degree or minimum 1 year experience in GMP industry