Job Description
Quality Assurance Associate II

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- Document control support of the IBITMS system including but not limited to:
    - Formatting of documents, publishing, completing DCR process
    - Document upload into IBITMS and full access servers
    - IBITMS course creation activities (acknowledgement, waiver, document publish, self-enrollment, cohort creation, assigning cohorts, new employee account setup, and IBITMS account installation and server access)
    - Document archive process
    - Annual document review including generation of list of documents due, issuing and tracking completion, document revision
    - Training assignments in IBITMS
- Issue batch record documents
- Scanning and filing of completed records including controlled documents, CCR, DCR, WO, NCs, CAPA, etc.
- Tracking and closure of Quality Management System records
- Perform shipping verifications as needed.
- Metrics- tracks and trends QA Quality Management System metrics
- Batch record review process: assembles and reviews all manufacturing and QCL related documents and data: As training progresses, disposition nonGMP batch records if all documents match written specifications and are accurate and complete in detail.
- Audits: Performs and supports Internal, Supplier, and Client Audits
- Supplier Quality – Performs Supplier Qualification activities including Supplier Qualification and monitoring/requalification, Supplier Quality Audits
- Reviews and provides input for Quality Management system elements including investigations and root cause analysis.

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
- Strongly desirable: knowledge of and ability to confirm compliance to US and EU GMP, USP, and Integrity Bio requirements.
- Validation strongly 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 a warehouse or office environment. Ability to lift 50 lbs.
- **Education and Professional Experience**
- Bachelor's Degree in Biochemistry, Chemistry, Microbiology, Molecular or Cellular Biology, or Biology.
- Minimum 1 year experience medical device or pharmaceutical industry supporting US/EU cGMP regulations.