

Quality Associate - Position Available 5/7/15

Job Description:

Integrity Bio is seeking a full time associate level candidate to support the Quality Assurance department in support of Integrity Bio's GMP Quality Management System.

Responsibilities:

- Processing received raw materials, components, etc. per Raw Material program including logging, quarantine, release, rejection statusing, sampling, issuing tracking forms ID testing or coordinating testing
- Ship raw or product samples to contract laboratory for testing
- Creation of Access-based document and related training tracking system. Tracking to ensure training completion, archiving records.
- Print, issue, and track labeling, manufacturing procedures, etc.
- Scan and archive various types of documents
- Maintain lot numbering assignments for production activities
- Support Operations in Supplier Qualification activities
- Support internal, client, regulatory agency, and customer audits including tracking and trending of audit findings
- Support creation/issuance/closure/scanning/archiving of Work Orders, Change Controls, Document Change Controls, Engineering Change Orders (dwgs, facilities) etc. records
- Manage supplier change notifications to IBI and IBI clients
- Track/trend/report on general Quality System Metrics
- Create and execute MS Access IOQ documents for e-forms

Experience and Professional Characteristics Requirements:

Communication Skills:

- Work well with others in a team environment
- Have strong skills for organization
- Able to easily follow a process or system
- Be a self-starter, and a self-motivator
- Demonstrates strong, professional written communication skills
- Excellent verbal communication
- Knowledge of US and ROW GMPs [Good Manufacturing Practices]
- Able to manage timelines and can handle multiple projects at the same time
- Able to troubleshoot issues

Computer:

- General fluency with computer systems
- Able to work easily with Microsoft office software

Physical Requirements:

- Ability to lift document binders (max 25 lbs) for short periods of time
- General physical activity required for laboratory environment

Education:

- BA/BS Degree or equivalent experience in pharmaceutical, biological, medical device or other heavily government regulated environment