

## Quality Specialist

Job Title:	Quality Specialist
Reporting To:	Quality Manager

### Job Purpose Statement

The QA Specialist is responsible for performing Quality compliance activities on the plant floor and ensuring that all activities are in compliance with company and regulatory guidelines and procedures. In addition, the QA Specialist is also responsible for assisting in activities directly related to batch release, and batch record and procedure review, revision and approval. The QA Specialist is required to consult with the Quality Management on all serious issues that may impact the company or product.

### Main Accountabilities

- Perform audits/checks of manufacturing, filling and packaging processes to include QA weight checks, line clearance activities, record review and signoff, cleaning verification label verification and reconciliation verification.
- Approve minor deviations on the operation floor.
- Review and approve executed batch records for completeness and accuracy for batch release.
- Review, revise and write batch records, procedures and policies in support of continuous Quality Improvement.
- Verify and ensure compliance with regulatory and company procedures and guidelines.
- Perform investigations as required.
- Assist in other quality related functions as requested, (sampling, component receipt and inspection, etc.)
- Additional tasks as assigned by Quality Management.
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### Job Related Qualification/Skills

- Bachelor's degree in a scientific or related discipline from an accredited college or university
- Minimum of 3-7 years' experience in the Pharmaceutical or Regulated Industry with prior experience in plant quality assurance.
- Demonstrated knowledge of cGMPs, ICH and other regulatory requirements for the manufacture, testing and release of pharmaceutical products.
- Strong proficiency in Microsoft Office suite of products, (Word, Excel, PowerPoint)
- Excellent verbal and written communication skills.
- Excellent interpersonal, communications and organizational skills as well as the ability to work independently.
- Occasionally lift 15-25 lbs. Must be able to stand for long periods of time.