



Manager, Quality Assurance

We have an immediate opening for Manager, Quality Assurance **Pharmaceutical Environment prefer.**

Please submit salary requirement with resume.

Scope of the job:

- Shared Management of Quality Assurance, Compliance and Validation in conjunction with 21 CFR Parts 210 & 211, Part 11, GMP and Good Manufacturing Practices.
- Assures that all operational and quality systems are appropriately documented and function in compliance with all regulatory requirements and internal SOP's.
- Manages Daily Departmental Operations for all Quality Assurance Areas and Validation.
- Oversees the preparation and approval of Quality & Validation Master Plans.
- Will develop Quality System improvements; interacting with directors, managers and supervisors; applying continuous improvement quality principles to all operating areas.

Responsibilities:

Management Responsibilities Include: QA Compliance, Final Document Review and Sample Coordination.

The position includes these responsibilities;

- Managing all aspects of Quality Assurance
- Contract Testing of Packaging Components
- Change Control Management
- Release of Finished Product Inventory
- Rejections
- Internal and External Audits
- Regulatory Agency Communication
- Review and Approval of SOP's, Customer Complaints, Investigations, Deviations, CAPA Planning & Execution, Master Packaging Orders, Annual Product Reviews.



- Regulatory Licensing, ARCOS and DEA Quota Applications.
- ERP System Compliance Support

Manages the following direct reports:

- QA Compliance Staff
- Final Document Review Staff
- QA Sample Coordinator

Qualifications:

- Bachelor's Degree in a related field.
- Minimum of 5 years' experience in Pharmaceutical Quality Assurance and Compliance. Experienced in GMP and application of 21CFR Parts 210 & 211 as well as Part 11 compliance.
- Ability to train and manage staff.
- Must possess ability to communicate verbally and in writing at all management levels.
- Familiar with a variety of the field's requirements, practices, and procedures.
- Relies on extensive experience and judgment to plan and accomplish goals.
- Performs a variety of tasks.
- Leads and directs the work of others at a management level.
- A wide degree of creativity and latitude is expected.
- **Must have a good command of the English Language, both written and verbal.**

Physical Demands:

- Must be able to sit, stand and walk for long periods of time.
- Must be able to spend long periods working at a computer and reading.
- Must be able to lift 30 pounds