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APPLY

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QA Manager

Location

Job Id#

OH

08791

About our client

Our client is a leading pharmaceuticals company.

Salary

Highly competitive package, commensurate with experience

Responsibilities

Partial Job Description

- 1) Manage a team of quality personnel
- 2) Conduct and/or evaluate internal auditing of all departments
- 3) Prepare, schedule and conduct audits of company suppliers to ensure conformance to regulatory standards and desired quality levels
- 4) Issue reports to audited suppliers and conduct follow-up as necessary
- 5) Prepare, host and manage all client, safety and governmental audits
- 6) Track and report planned and unplanned deviations and out of specification (OOS) trends
- 7) Conduct various routine tasks to maintain an effective QA/QC system
- 8) Ensure all company employees are trained on necessary policies and procedures, conduct BPP training, GMP training, Safety training and tour and chemistry general skills training.
- 9) Develop and maintain continual training program
- 10) Train evaluations, develop and maintain training metrics and train files
- 11) Create, revise and review the standard operating procedures for all departments, including revising table of contents and assigning of SOP numbers
- 12) Facilitate creation of new documents to ensure continuous/process improvement
- 13) Ensure company is within NFPA, OSHA, SARA and DOT regulations on a local, state and federal level when an issue arises, which includes training, labeling, MSDS, accident reports, fit testing and review of safety plans and radiation inventory reports
- 14) Monitor quality and safety goals over time and develop action plans to optimize and evolve both programs effectively under current governmental and client regulations
- 15) Initiate and manage out of specification investigations for all client inquires and complaints
- 16) Determine the root cause of the issue and consult with the supervisors for corrective actions
- 17) Maintain Master Validation Plan protocols
- 18) Research, create, implement and/or improve validations and verifications

Requirements

Qualifications / Skills Required

- 1) BS or MS in Chemistry or related science
- 2) Minimum 5 – 10 years of experience in a pharmaceutical Quality Assurance Department
- 3) cGMP and GLP experience
- 4) Previous supervisory experience
- 5) Experience in hosting and managing FDA audits
- 6) Experience and familiarity in USP/NF methods
- 7) Experience in an FDA regulated environment
- 8) Worked in a laboratory setting (GLP)
- 9) Ability to develop technical plans and programs to ensure an efficient, safe and high quality laboratory operation
- 10) Ability to work independently, self-motivated and strong attention to detail
- 11) Ability to present facts and recommendations effectively in oral and written form
- 12) Strong interpersonal skills such as communication, relationship building, leadership, initiative, adaptable, positive attitude and team building

APPLY

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