QA Associate II

Job Description

The Quality Assurance Associate II is responsible for providing compliance and regulatory support to all aspects of the organization to maintain the quality management system.

Key responsibilities include but not limited to the following;

- Provides guidance with resolving, Non-Conformances, Corrective/Preventative Actions, Deviations and execution of Change Controls
- Reviews production batch records and associated data for product disposition and release
- SOP revision, review and creation
- Performs Line Clearances for cGMP processes
- Conducts Internal and External GMP Audits and Audit follow up
- Monitors and maintains training records and programs
- Assures products, materials and processes, and related documentation, are compliant and harmonized within the quality management system
- Provides document control support as necessary

Required Qualifications

- Solid background in FDA and ISO regulated Quality Management System
- Proficient in MS suite (Word, Excel, PowerPoint and Outlook) and Adobe software
- Exceptional written and verbal communication skills
- Strong scientific knowledge relating to the Pharmaceutical and Medical Device Industry

Preferred Qualifications

- Able to perform Product Impact and Risk Assessments
- Able to revise, organize and create APR reports

Education and Experience

Typically requires a Bachelor's degree or the equivalent training and experience in a science or closely related discipline with, 2-5 years of experience in pharmaceutical, medical device or biotechnological related field.

Compensation and Benefits

This is a full-time position with medical/dental insurance provided and an hourly compensation ranging from 25-29/hr. based upon education and experience.

Job Type: Full-time

Salary: $25.00 to $29.00 /hour