Quality Assurance Specialist

The Quality Assurance Specialist is responsible for the execution of quality systems supporting Manufacturing Operations and includes the review of cGMP documentation, including batch records, Standard Operating Procedures, Quality Control test results, calibration records, environmental and utility data review and Certificates of Analysis. The Quality Assurance Specialist is also responsible for document control functions including, routing and tracking of GMP documentation, GMP investigations, variances, change controls, CAPAs, and document control activities.

Educational/Experience Requirements:

- Bachelor of Science degree in Natural Sciences, Pharmacy, or Engineering from an accredited college/university required or equivalent experience
- 3-5 years of GMP Quality Assurance experience, preferably in an aseptic manufacturing operation

Other Skills and Abilities:

- Working knowledge of cGMP, 21CFR, USP and other applicable regulations, standards and guidance
- Knowledge of deploying quality systems within pharmaceutical and/or biologics industries
- Strong analytical skills with proficiency in the application of problem-solving and root-cause analysis methodologies
- Strong writing skills and the ability to communicate complex ideas and concepts
- Experience in aseptic manufacturing processes and relevant sterility assurance programs for sterile pharmaceutical products
- Strong attention to detail, i.e. reviewing documentation for adherence to SOP format requirements; accurate data entry of documentation into database.
- Knowledge of cGMP auditing practices
- Experienced user of Microsoft Word, Excel, and Powerpoint

To Apply

To apply for a position posted on this site, please send an attachment of your resume electronically to resumes@discoverylabs.com

Due to high volume, only those applicants who meet the minimum qualifications will be contacted for an interview. All applications received for valid positions will be acknowledged electronically. No phone calls please. Resumes will be kept on file in the Human Resources department for six (6) months from the date of submission.

Discovery Labs is an equal opportunity employer, M/F/D/V.