Job Description Form
Job Description # JD167

Job title: Quality Associate – Batch Release
Department: Quality Assurance and Regulatory Affairs
Location: Bloomington, IN
Position Type: Full-time, exempt
Reports to: Quality Manager

General Description:
The Quality Associate – Batch Release is responsible for managing the workflow of records for Manufacturing activities in accordance with company and client quality standards, including the appropriate disposition of materials or manufactured product. Additionally, this position will be responsible for providing oversight to Quality Control/Development Laboratory operations, including the review and disposition of raw material, in-process, release and stability testing.

1. Responsible for the issuance, review, and release of batch records and protocols. Ensure records are executed in accordance with procedures and regulatory requirements.
2. Collaborate with various departments to ensure record specifications are accurate and related deviations are thoroughly investigated.
3. Interface with clients to provide support for review and release of records related to client material or product.
4. Generate and issue controlled labeling material for manufacturing operations. Review for legibility, accuracy, and compliance to company, client, and regulatory standards.
5. Review and disposition Quality Control/Development Laboratory records, including experimental data, analytical data, laboratory reports, and environmental monitoring data.
6. Responsible for the development and issuance of Quality operational metrics.
7. Serve as the Subject Matter Expert (SME) on Manufacturing and Quality Control/Development Laboratory record workflow, including applicable SOP revisions and process improvements.
8. Assist with the completion of internal audit activities and provide support for client audits as needed.
9. Must perform other duties as assigned by the Manager. Responsible for notifying the Manager when issues arise.
10. Comply with quality and safety management systems including requirements for documentation, training, system use, SOPs, processes, and procedures.
11. General support required of a company where everyone is expected to perform multiple tasks both inside and outside their department to meet the needs of the business.

Skills Requirements:

1. Excellent internal and external communication.
2. Ability to make independent decisions, as well as work within a team.
3. Good time management and organizational skills.
4. Detail orientated, must be able to perform thorough reviews of documentation.

Education and Work Experience Requirements:

1. Bachelor's degree required, preferably within a scientific discipline.
2. 3-5 years QA/QC experience preferred.
3. Must possess knowledge of Good Documentation Practices (GDP).
1. Experience in an aseptic manufacturing and laboratory operations is desirable.

Singota Solutions is an Equal Opportunity Employer