Job Description Form
Job Description # JD185

Job title: Quality Associate 1 – Batch Release
Department: Quality Assurance and Regulatory Affairs
Position Type: Full-time, exempt
Reports to: Associate Quality Assurance Manager

General Description
The Quality Associate 1- Batch Release is responsible for managing the workflow of records for Manufacturing and QC/Development activities in accordance with company, client and regulatory quality standards, including the appropriate disposition of materials or manufactured product. This position is responsible for reviewing records for accuracy and completeness and for identifying discrepancies or issues that could result in product impact.

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. Perform disposition of materials within the electronic inventory management system, issue appropriate release documentation.
3. Collaborate with various departments to ensure record specifications are accurate and related deviations are thoroughly investigated.
4. Interface with clients to provide support for review and release of records related to client material or product.
5. Author deviations, CAPAs and change controls as needed.
6. Generate and issue controlled labeling material for manufacturing operations. Review for legibility, accuracy, and compliance to company, client, and regulatory standards.
7. Review and disposition Quality Control/Development Laboratory records, including but not limited to, Electronic Lab Notebook (ELN) experiments and environmental monitoring data.
8. Responsible for the development and issuance of Quality operational metrics.
9. Write and review Standard Operating Procedures related to Quality Systems within Manufacturing and QC/Development.
10. Represent Quality Assurance at various project and technical meetings.
11. Must perform other duties as assigned by the Supervisor. Responsible for notifying the Supervisor when issues arise.
12. Comply with quality and safety management systems including requirements for documentation, training, system use, SOPs, processes, and procedures.
13. 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 and Physical Activity Requirements:

1. Excellent internal and external communication.
2. Demonstration of positive attitude and professional presence.
3. Good time management and organizational skills.
4. Detail orientated, must be able to perform thorough reviews of documentation.

Work Experience and Education Requirements

1. Bachelor's degree or equivalent experience – science related field preferred.
2. Minimum 1-3 years pharmaceutical experience is desired, preferably in a Quality role.
3. Must possess knowledge of Good Documentation Practices (GDP).
4. Experience in an aseptic manufacturing desirable.

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