# Job Description Form
**Job Description # JD141**

**Job title:** Quality Associate 1 - Operations
**Department:** Quality Assurance and Regulatory Affairs
**Position Type:** Full-time, exempt
**Reports to:** Quality Assurance Supervisor

**General Description:**
The Quality Associate 1-Operations position provides Quality oversight, assistance and guidance in daily operations related to Supply Chain Management and Manufacturing. This position is primarily responsible for ensuring compliance and accuracy of all documentation and data related to the release of materials for shipping and receiving. This role is also responsible for providing oversight and in-process reviews of Manufacturing batch records and related documentation. This role must also positively interface with internal key stakeholders, clients and regulatory agencies regarding quality and regulatory issues.

1. Provide on the floor QA support for Manufacturing and Supply Chain including in-process batch record review, room release, equipment release, logbook and documentation review, and process oversight.
2. Perform and/or oversee quality inspections including, but not limited to: labels, components, filled vials, and packaging.
3. Assist with the review of sampling, dispensing, shipping, and receiving material packets for GDP adherence.
4. Perform Acceptable Quality Limit (AQL) sampling on products/materials and maintain visual inspection qualification status.
5. Collaborate internally as well as with applicable suppliers to provide oversight for shipping qualification studies. Oversight includes review and approval of supplier provided protocols and reports.
6. Perform status change of material and/or finished product per the validated inventory management system.
7. Become gowning qualified to perform Quality functions within the cleanrooms (line clearances, batch execution support).
8. Process shipments and receipts of controlled substances, maintain qualification status as controlled substance authorized personnel.
9. Represent Quality Assurance at various project and technical meetings, as needed.
10. Author deviations, CAPAs, and change controls as needed.
11. Write and review Standard Operating Procedures related to Quality systems within Supply Chain Management and Manufacturing.
12. Perform other duties as assigned by the Quality Manager. Perform all responsibilities in accordance with company guidelines and Standard Operating Procedures and appropriate industry and regulatory standards and guidelines.
13. Comply with quality and safety management systems including requirements for documentation, training, system use, SOPs, processes and procedures
14. Work in collaboration with other departments to meet the needs of the business.

**Characteristics required include:**

1. Demonstration of positive attitude and professional presence.
2. Strong work ethic and the ability to work in a fast-paced environment.
3. Demonstration of good organizational and time management skills.
4. Good communication skills, adept at working individually and as a team.

**Work Experience and Education Requirements and Preferences:**

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. Experience with aseptic manufacturing and supply chain operations is highly desirable.

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