Job Description Form
Job Description # JD141

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

General Description:
The Quality Associate-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 position is responsible for evaluating and resolving process issues by collaborating with Manufacturing and Supply Chain Management personnel to ensure product and material safety is protected. 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 with other departments to utilize and improve strategy, processes, tools, training, SOPs, etc.
10. Participate in training of new Quality Assurance staff.
11. Execute deviation investigations, CAPAs, and change controls as needed.
12. Write and review Standard Operating Procedures related to Quality systems within Supply Chain Management and Manufacturing.
13. 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.
14. Comply with quality and safety management systems including requirements for documentation, training, system use, SOPs, processes and procedures
15. 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. Ability to make independent decisions regarding quality related concerns or issues.
4. Demonstration of good organizational and time management skills.
5. Ability to author and review technical documents.
6. Good communication skills, adept at working individually and as a team.

Work Experience and Education Requirements and Preferences:

1. Bachelor's or Associate's Degree in a science related field preferred.
2. Experience in Quality Assurance, Manufacturing, or Supply Chain Management is desirable.
3. Knowledge of Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP) desired.

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