Quality Assurance and Regulatory Affairs Manager

The Quality Assurance and Regulatory Affairs Manager will drive the strategic and operational performance of the Quality department in the St. Charles, Mi. location. This position ensures the successful delivery of business strategy and operational goals to exceed customer expectations for product quality, customer service, engineering quality, cost and delivery, while facilitating continuous improvement and achieving commercial success. Applies Lean Manufacturing methods and applies statistical process control techniques to improve the statistical process capability (cpk) of the batch-manufacturing and packaging systems. The Manager will lead and manage the quality team and ensure the efficient and effective day to day running of the department.

The Quality Manager must be a change agent and possess hands-on management skills.

Job Functions include but are not limited to:

- Lead the development and execution of strategic plans to meet departmental and organizational goals while complying with regulatory and customer requirements.
- Strong customer-facing communicator and negotiator. Timely, reliable responsiveness to complaints, questionnaires or other Quality Assurance concerns with other departments. Facilitate exchange of information in order to implement change and improvements regarding quality.
- Lead, develop and coordinate the requirements necessary to meet ISO, FDA-GMP and customer audit compliance in the most cost-effective manner.
- Manage the routine activities of the Quality Laboratory including: a) selection, development, evaluation, motivation and retention of qualified personnel; b) operation of the department within appropriate budgetary constraints; c) consistent administration of Company policies and procedures; d) maintenance of an orderly work environment.
- Create and develop detailed action plans that direct Operations and Engineering to improve the quality of products and reduce waste and scrap. Administration and coordination of the Customer Complaint System including assuring timely communication with the customer, sales, manufacturing, engineering and other personnel.
- Leads Continuous Improvement initiatives and applies root-cause problem-solving techniques to improve product quality, to reduce costs and to minimize waste. Understands the production processes, the chemistry and the inter-relationships.
- Provide leadership and guidance to assure corrective actions are resolved, adequate root cause analysis is completed and short/or long-term corrective actions are implemented.
- Continually partner with Product Development Scientists, Commercial partners, Engineers and customers to develop specifications to ensure that customer requirements and company specifications match. Resolve contradictions with customer's specifications and procedures.
- Identify and pro-actively lead continuous improvement actions to prevent non-conformances; work closely with internal and external customers.
- Provide progress reports/Quality Key Performance Indicators (KPIs) to Senior Management.

- Develop, implement, and maintain Quality Systems.
- Drive key performance indicators to all levels within the organization related to Operation's delivery of product quality and Quality Assurance. Make recommendations for necessary changes to enhance the business objectives.
- Prepare and conduct formal management review meetings and follow up.
- Responsible for publishing and approving documents. Maintaining and continuously improving quality system processes as required by international, regional and national regulatory authorities and standards, ISO 9001 and FDA QSR.
- Functioning as the leader and management representative during audits, internal and external.

Education:
Bachelor's degree or equivalent training and/or experience, with focus on areas of science, engineering and/or business administration.

Experience:
- 10 to 15 years experience related to Quality/Regulatory System Development and Management.
- 5+ years of experience working in an FDA regulated environment.
- 5 to 10 years experience managing people

Other skills and abilities:

- Understanding of FDA's Quality System Requirements, 21CSR820, ISO 9001 and ISO 13485.
- Knowledge of other regulatory processes: 510K, process validation and statistical quality tools.
- Excellent oral and written communication skills.
- Excellent leadership skills.
- Practical knowledge of Design or Experiment (DOX) lean manufacturing, Six Sigma and team problem solving.
- Plex, SAP or related business enterprise system
- Microsoft Office Suite skills including Excel and PowerPoint.

To apply for this position, click here

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