Purpose Statement:

Leads a team of Managers, Engineers, Technicians and other QA professionals to ensure the efficient production / assembly, complaint investigation, and quality system execution in accordance with Global / site procedures in full compliance to all GMP/QSR practices and standards as defined by the Food and Drug Administration, ISO Standards, and other regulatory bodies. Collaborates with R&D and Manufacturing Engineering on new product introductions and sustaining projects.

Key Responsibilities

- He/She will provide leadership and direction to his/her team and ensure a Quality Management System exists to meet the various requirements of a medical device manufacturing facility. Specifically, he/she will ensure that the necessary monitoring of environmental controls, management of documentation process's including storage, retention and review, support of internal auditing programs, verification of all products and process to the established quality standards through 100% testing or statistically valid sampling. Validation of new products/process's or changes to existing products/process's, and support of a vendor review and rating systems are in place on Site.
- He/She will build a strong and sustaining relationship with Production, Engineering, Corporate QA/Regulatory, external Regulatory bodies and others and will be recognized as an excellent team player within the total organization on site.
- He/she will be committed to developing people and is recognized as an expert in mentoring and coaching individual and team performance while visibly demonstrating the core values of BSC in his/her everyday leadership style.
- He/she will continuously foster and drive a continuous improvement approach to Quality on Site ensuring that quality is the responsibility of everyone - not just the QA department and that the Quality System is an integrated and integral aspect of the total running of the Site.
- He/She will be the designated Management Representative providing quality oversite, ensuring quality objective are established and monitored, and provide visibility to quality performance to management with executive responsibility.

Additional responsibilities include:

- Leads, coaches, and develops department team members as necessary to support changing business needs
- Works with the Operations and Manufacturing Engineering to drive continuous improvement through business and quality objectives
- Provides Quality Engineering support for production; addresses non-conformances through the NCEP system, driving PIR escalation and PIR processes when risk level warrants
- Collaborates with cross-functional teams on new product introductions, transfers, and sustaining projects with a focus on Design for Manufacturability / Testability / Reliability
- Supports all aspects of the supplier qualification program; including supporting indirect team for supplier audits and associated follow-up activities
- Provides support to IQA function in dealing with non-conforming materials
- Leads Quality Planning activities related to Quality System Integration projects, Improvement projects, QMPs & other site projects as needed

- Drives improvements in product quality based on out-of-box failure / complaint / in-process data analysis
- Leads corrective and preventive actions as required; proactively identifies and executes on opportunities for preventive actions
- Leads cost reduction projects, using Lean / Lean Business Process methodologies; contributes annually to the VIP savings program through Quality-driven projects as well as supporting projects driven by other functions
- Participates in site internal audits and facilitates external audits
- Contributes to Quality Management Reviews
- Ensures training plans and records for direct reports are compliant to Company-specific policies

Quality System Requirements

- In all actions, demonstrates a primary commitment to patient safety and product quality by maintaining compliance to the Quality Policy and all other documented quality processes and procedures.
- Assures that appropriate resources (personnel, tools, etc.) are maintained in order to assure Quality System compliance and adherence to the BSC Quality Policy.
- Establishes and promotes a work environment that supports the Quality Policy and Quality System.

Qualifications

- Bachelors of Engineering, Science or technical degree and related development and design experience in the medical device with a minimum of 12 years in FDA regulated industry (or equivalent combination of experience and education)
- Minimum 10 years people management experience
- Ability to interact with senior leadership across the organization
- Must have demonstrated leadership, coaching, employee development, influencing, and negotiation skills
- Experience with Lean/Lean Business Process (LBP methodology
- Demonstrated presentation and facilitation skills required
- Proven history of driving process improvements. Process excellence experience and experience leading change management projects.

Preferred Qualifications

- Master's Degree in Engineering/Science or MBA preferred
- Experience managing quality functions within Boston Scientific Quality Systems and business processes