**TITLE:** Director, Quality
**DEPARTMENT:** Quality Control - MA
**REPORTS TO:** Chief Operating Officer
**DATE:** 01DEC2022
**STATUS:** Exempt
**LOCATION:** Wilmington

**Job Summary:**

Lead the Quality organization (QA & QC) and will assure the site remains under control with respect to GMP, collaborating with Operations to solve quality issues. Accomplishes corporate business objectives by developing site quality systems and enforcing Quality compliance. Responsible for providing the strategic leadership and management for the Site`s Quality organization. Provide leadership to the Site Quality organization to ensure that teamwork, high morale and innovation are fundamental components of a team. Ensures alignment with customer needs and linkage with the overall Quality and business strategies.

**Essential Duties and Responsibilities:**

- Manage, direct and support the Quality Control team. Hire, train, develop, teach, coach, mentor, motivate, discipline, and reward staff members.
- Meet regularly with direct reports to review performance, identify any issues, and set expectations of goals.
- Leads & supports Audits & Regulatory Inspections at the Site
- Leads and directs staff in both QA and QC and ensures their development
- Manage, direct, and support the QC/QA teams. Hire, train, develop, teach, coach, mentor, motivate, and discipline staff members.
- Meet regularly with direct reports to review performance, identify any issues, and set expectations of goals.
- Develops compliance related manufacturing and process controls and improves quality systems
- Develop strategic plans that incorporate regional and/or global practices and customer needs. Develop effective project milestones, schedules, and manage budgets, including capital. Identify and resolve issues that may jeopardize project schedules or improve project timelines.
- Holds responsibility for Quality budget and driving Operational Excellence
- Member of the Site Leadership team
- Provide strategic direction and oversight of the Quality Management System.
- Ensure performance and quality of products conform to established company and regulatory standards.
- Maintain up to date knowledge in Microbiology and Quality System Standards and ensure implementation in company processes.

- Manage all aspects of product sterilization from validation through product release. Validate and upgrade sterilization processes and supporting ancillary systems (e.g., water system) in accordance with industry standards.
- Provide expert advice to management regarding quality/compliance issues.
- Oversee in all third-party (FDA, ISO, etc.) audits and inspections. Serve as management representative.
- Utilize statistical techniques, develop, analyze and deliver periodic reports on KPIs and Quality Metrics
- Support new product development teams and design control activities
- Maintain Supplier Quality Program.
- Other responsibilities as assigned.

**Qualifications:**

- Bachelor's Degree in Engineering or Microbiological Science, and/or another scientific discipline.
- Comfortable driving multiple initiatives at a rapid pace, and making thoughtful recommendations with available data.
- Active, effective communicator who drives a company vision/mission to align teams, critical resources, management, and stakeholders.
- Demonstrated ability to monitor the work of direct reports to ensure quality, accuracy, and thoroughness.
- 10+ years of QA related experience. At least 8 years should be in a QA leadership role in a medical device company.
- Previous orthopedic experience strongly desired.

**Skills, Abilities, Competencies Required:**

- Able to monitor the work of direct reports to ensure quality, accuracy, and thoroughness.
- Excellent written and verbal communication skills; able to communicate effectively and appropriately with internal and external stakeholders.
- Willingness to make decisions; build commitment for decisions and overcome resistance from others.
- Able to work independently as well as part of a team; demonstrated experience building a strong team environment.
- Demonstrated original thinking and able to generate creative solutions; identify and resolve problems in a timely manner.
- Able to excel in a high-pressure, fast-paced, and ever-changing environment; adapt to frequent changes, delays, or unexpected events while meeting objectives, budgets, and timelines.
- Strong interpersonal skills and maturity in working with all levels of the organization.
- Extensive and comprehensive understanding of US FDA regulations and ISO 13485 requirements.
- Experience in EU MDR.

- Experience in sterilization process management including validation.
- Experience with machining and mechanical device and software validations.
- Experience as the lead liaison for FDA and ISO audits/inspections.
- Excellent investigation and writing skills; ability to write procedures, work instructions, etc.
- Computer skills, including WORD, Excel, etc.

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