Director of Quality Systems

POSITION SUMMARY:
Reporting to the VP Global Quality Assurance and Regulatory Affairs, The Director of Quality Systems has primary responsibility for the management of the written quality system within all Sterigenics facilities. These facilities are primarily engaged in EO and/or radiation sterilization processing and laboratory services. The Director of Quality Systems is to implement the company quality strategy and initiatives and to ensure compliance to applicable global standards and regulations.

DUTIES AND RESPONSIBILITIES:

Regulatory Affairs (RA):

- Interpret and provide subject matter expertise with applicable Global Regulations and ISO Standards for Sterigenics.
- Maintain current facility Drug Master Files (DMF) and Master Files for Devices (MAF).

Quality Systems:

- Ensure the management and maintenance of the Quality System
    - Implement programs to ensure efficient and effective compliance with regulations and standards across sites that service medical devices, pharmaceuticals, foods, and tissues.
    - Implement and maintain systems to ensure continuous improvement of the QS.
    - Develop, review, and approve appropriate levels of the Quality System.
    - Champion the management review process, including developing materials for the reviews.
    - Proactively work with Sterigenics sites on quality system continuous improvement opportunities.
    - Monitor quality systems integrations for progress and compliance.
- Provide subject matter expertise and technical support to Sterigenics senior staff and facility management.
- Single Point of Contact for Sterigenics with the company's Notified Body
- Support facilities during internal and external audits and in response to internal and external audit findings to ensure continual positive outcomes and consistency across the Sterigenics network.
- Manage the Sterigenics Document Management System, including change control and records retention processes.

Software Validation:

- Responsible for strategy and leadership for software validation program for Sterigenics
    - Ensure systems and procedures are in place to facilitate compliant software validation
    - Provide oversight and subject matter expertise for software validation process and documentation.
      Provide guidance on software validation and Part 11 matters for global Sterigenics Regulatory Training Program:

Other Items

- Identify, develop, deploy, and manage training programs to facilitate regulatory compliance (e.g., GMP training).
- Oversee, motivate, mentor and evaluate Quality Managers, and their employee's performance and provide input, as appropriate, for performance appraisals.
- Direct involvement in the Hiring, Firing, and Discipline of all Quality Assurance personnel within the Quality Systems organization.

- Monitor activities to ensure compliance with core quality measures.
- Gather, analyze and manage quality related data and participate in site and Corporate management reviews.
- Direct responsibility for the Global implementation of the company's Quality System.
- Partner with OpEx team to be a Sterigenics leader in continuous improvement by learning, utilizing and teaching Operational Excellence tools.
- In conjunction with the OpEx team, ensure there is a dynamic project list, inclusive of quality and compliance projects that drive improvement across sites and the regions.
- Going to Gemba and spending time in the sites is required.
- Ensure compliance with global regulatory bodies, including but not limited to FDA, EU GMP, ISO, MHLW/JPAL, USDA and MHRA
- Lead programs to ensure continuous operational quality improvement as measured by quality metrics and reported to appropriate levels of management
- Provide technical support regarding the quality management system to senior staff and facility management
- May represent Sterigenics on national standards groups (AAMI, ASTM) as appropriate
- Participate in the development of QA staff with the potential to advance into higher positions
- Prepare and understand, as required, budgets and financial plans for the Quality organization. Meet budget responsibilities in the QA operating plan.
- Other items as assigned.

SUPERVISION GIVEN:

The site Quality Assurance Managers report indirectly to the Director Quality Operations. Partnering with the site General Managers, the Director Quality Operations is responsible to oversee, motivate, mentor and evaluate the QAMs and their employee's performance. Strong lateral leadership and influencing skills are needed in this position.

EDUCATION, EXPERIENCE & SKILL REQUIRED:

- Bachelor's Degree, preferred in a technical discipline
- Ten (10) or more years Quality leadership experience in a regulated environment (pharma / medical device preferred) with a proven track record of success.
- Experience in developing and implementing quality systems for compliance with FDA device and pharmaceutical requirements.
- Project management experience required.
- Sterility Assurance experience preferred.
- Multi-site experience required
- Proven track record for identifying and implementing continuous improvements
- Strong technical aptitude, analytical and problem-solving skills
- Excellent verbal and written communication skills
- Success working with multifunctional, global teams with strong lateral leadership and influencing skills.
- Excellent interpersonal/communication/influencing/negotiation skills required
- Demonstrated analytical, problem solving and CAPA documentation skills
- Success working in high pace environment
- Regular attendance is required

SPECIAL REQUIREMENTS:

Domestic and international travel is required up to 20%.

TRAINING REQUIRED:

Director Quality Systems must understand global quality system requirements and have a working knowledge of Sterilization and or irradiation techniques. Also must have a working knowledge of Global Medical Device Regulations and Global Pharmaceutical requirements. Must have Auditee and Auditor experience. Must be well versed in management techniques along with a solid business acumen.

All qualified applicants will receive consideration for employment and will not be discriminated against on the basis of race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, or protected veteran status. Sterigenics U.S. LLC takes affirmative action in support of its policy to employ and advance in employment individuals who are minorities, women, protected veterans, and individuals with disabilities.

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