SterileCare

We Are Hiring

Manager, Quality Assurance & Regulatory Affairs

About the Role

A reliable **Manager of Quality Assurance and Regulatory Affairs (QA/RA)** ensures that all external and internal requirements are met before our product reaches our customers. You will be responsible for inspecting procedures and outputs and identifying mistakes or non-conformity issues in the quality system and in the product. You will also play a key role in devising procedures to inspect and report quality assurance issues and monitor all operations that affect quality. The QA/RA Manager will also perform the role of Management Representative (MR) as per ISO 13485.

An excellent QA/RA Manager has eyes like a hawk and solid experience in quality control and regulatory affairs. The ideal candidate is a reliable and competent professional whose approval will be necessary for the continuation of a business life cycle. It involves monitoring and advising the performance and maintenance of a quality management system, producing data, measuring quality operations against set standards, and meeting regulatory requirements for each market. You will be required to keep up to date with changes in regulations that affect the product and in maintaining approvals and registrations.

The goal is to assure the high quality of our operations and services aiming to the long-term success of our business. The QA/RA Manager will make sure the business remains productive/profitable by implementing and monitoring programs that ensure continuous quality while managing risk.

What You Will Be Doing

- Maintains proper control over critical approved suppliers including contract manufacturer and distributors.
- Achieves quality assurance operational objectives by contributing information and analysis to strategic plans and reviews; preparing and completing action plans; implementing production, productivity, quality, and customer-service standards; identifying and resolving problems; completing audits; determining system improvements; implementing change requests.
- Develops quality assurance plans by conducting hazard analyses; identifying critical control points and preventive measures; establishing critical limits, monitoring procedures, corrective actions, and verification procedures.
- Validates quality processes by establishing product specifications and quality attributes; measuring production; documenting evidence; determining operational and performance qualification; writing and updating quality assurance procedures.
- Maintains and improves product quality by completing internal audits hosting and responding to external audits; investigating customer complaints; collaborating with other members of

management to develop new product and engineering designs, and manufacturing and training methods.
- Prepares quality documentation and reports by collecting, analyzing and summarizing information and trends including failed processes, stability studies, recalls, corrective actions, and re-validations.
- Updates job knowledge by studying trends in and developments in quality management and industry standards through continuing education opportunities; participating in educational opportunities and workshops; reading professional publications; maintaining personal networks; participating in professional organizations.
- Enhances department and organization reputation by accepting ownership for accomplishing new and different requests; exploring opportunities to add value to job accomplishments.
- Assure the reliability and consistency of production by checking processes and final output.
- Delivers reports and presentations regarding the quality system to the senior management.
- Responsible for assuring regulatory and internal compliance across all aspects of manufacture, use, servicing, transportation, storage and disposal of the product.
- Provides regulatory support related to medical device licenses and certifications.
- Compiles information and maintains post-market surveillance documents.
- Registration support for international countries.
- Lead or assist FDA applications/submissions.
- Provides sales and Marketing support when required.
- Appraise customers' requirements and make sure they are satisfied.
- Facilitates proactive solutions by collecting and analyzing quality data.
- Reviews current standards and policies.
- Maintains records of quality reports, statistical reviews and relevant documentation.
- Directs and supervises vendor-supplied raw materials or partially finished goods, maintaining effective compliance and corrective action procedures.
- Oversees product recalls, advisory notices and vigilance reporting when products fails
- Reviews all quality agreements with suppliers.
- SR&ED: SCI may assign this role some responsibility for R&D activities.
- Manages departmental budget and tracks all related expenses.
- Maintains confidentiality of sensitive data.

Management Representative (MR) Rsponsibilities

- Maintains all certifications (including but not limited to ISO 13485, CE Mark, MDSAP, annual Health Canada Medical Device Licence, FDA).
- Communicates with Notified or Regulatory Bodies as well as Authorized Representatives; with quality consulting bodies if required.
- Conducts annual Management Review Meetings and provides risk management recommendations.
- Leads all annual internal and external audits including microbiology audits.
- Manages records which are a direct output of the quality management system required for ISO 13485 Certification, including change requests, complaints, corrective and preventive action (CAPAs), Non-Conformities (NC's) record maintenance related to audits, document control and product activities as well as post market surveillance.
- Maintains Initial and ongoing annual supplier evaluations.
- MDR transition (Person Responsible for Regulatory Affairs).
- Trains SterileCare's employees and consultants on QMS.

Production/Manufacturing Activities:

- Labelling control for product.
- Quality contact for production including maintaining all protocols/reports/CoAs with CMO and Testing Laboratory .
- Develops strategy from beginning to end for the development of new product variations.
- Performs ongoing stability commitment and testing to support current shelf-life and investigate shelf-life extension.
- Product release after review of batch records and testing of specifications.

- Maintenance of Medical Device File, Product Specification, Development Plan (input-output).
- Protocol creation, review of results – determination of trends.

Research and Development Activities

- Responds to product queries on website and disseminate scientific information if requested.
- Assists with development of clinical trials/evaluations.
- Conducts protocol writing and review when required.
- Conducts literature review and assessment of the competitive landscape.
- Assists with poster and manuscript writing when required.

Your Work Environment

Home office is the primary work environment and occasional visits to head office in Markham for strategic meetings, internal/external audits as well as management review meetings.

What You Will Need

- A Bachalors degree in any relevant field of science or engineering. A graduate level degree would be an asset.
- Demonstrated problem solving abilities both while working alone or as a team.
- Ability to examine and implement process improvement initiatives.
- Proven experience as a quality assurance manager or relevant role under an ISO 13485 compliant QMS.
- Thorough knowledge of methodologies of quality assurance and standards.
- Excellent numerical skills and understanding of data analysis/statistical methods.
- Good knowledge of MS Office and databases.
- Outstanding communication skills.
- Great attention to detail and a result driven approach.
- Excellent organizational and leadership abilities.
- Reliable and Trustworthy.

Working at SterileCare

As a Canadian virtual manufacturer, we have excelled at working remotely and supporting a remote work model that provides flexibility, fosters teamwork, communication and execution excellence. We offer competitive compensation, a comprehensive benefits package and a generous vacation package.

SterileCare is an equal opportunity employer and values diversity. We are committed to providing accommodation for people with disabilities. Please let us know if you require accommodation due to a disability during any aspect of your candidate experience and we will work with you.

How to Apply

Send us your resume and cover letter to **info@sterilecareinc.com**. Indicate Manager of Quality Assurance & Regulatory Affairs in the subject line. Thank you in advance to all applicants for your interest in SterileCare.

Scan to Apply