JOB TITLE: Director, Regulatory Affairs & Quality Assurance for Medical Devices

POSITION SUMMARY

Reporting directly to President, responsible for creation, implementation and maintenance of the Quality System processes, in compliance FDA 21 CFR, Part 820, Quality System Regulation and ISO 13485. Manage all aspects regulatory compliance. Correspond with FDA and EU notified bodies. Prepare and maintain international product registrations. Filling facility registration and Device Listings. Maintenance of regulatory files, consistent with state, federal and international regulatory requirements. Acts as Management Representative in reporting to management on performance measures for quality improvements and compliance. Provide knowledge and support to the company to enable company to operate within regulatory guidelines.

RESPONSIBILITIES

1. Develop regulatory strategies for U.S. and Canadian markets.
2. Serve as Official FDA Correspondent.
3. Host FDA and regulatory agencies audits.
4. Complete annual registrations.
5. Review and interpret regulatory rules as they relate to company products and processes. Set up Quality System policies and procedures to ensure is in compliance with FDA 21 CFR, Part 820, Quality System Regulation and EU requirements.
6. Conduct ongoing company-wide trainings on FDA and ISO requirements.
7. Assess need for regulatory registrations and act accordingly.
8. Responsible for the Document Control process and the efficient control of all documentation required by regulatory agencies.
9. Sets-up and oversees inspection and Device History Records activities.
10. Define needed quality metrics and coordinate data collection from various functions.
11. Perform Management Reviews and advise management of any product or process related issues and make recommendations for improvements.
12. Plan and manage internal audit activities and coordinates audit corrective actions.
13. Manage the CAPA process and ensures corrective actions are established and that root-cause elimination is completed for identified issues.
14. Manage the Complaint Handling process and Medical Device Reporting activities.
15. Manage the Nonconforming Material process. Overlook the administration and disposition of nonconforming materials.

16. Administer and manage supplier qualification activities and monitor suppliers' performance.
17. Promote a positive working environment conducive to a team atmosphere.

SUPERVISORY RESPONSIBILITIES

- Supervise inspectors and Quality Specialist.
- Exhibit skills in project management, leadership, communication and presentations.
- Identify issues and minimize regulatory risks through creative problem solving.

QUALIFICATIONS AND SKILLS REQUIRED

- Minimum of 10 years of Quality Management, Quality Assurance and Regulatory Affairs leadership experience in the medical device industry, with responsibilities for managing others.
- Experience with FDA and EU device and facility registrations.
- A four-year degree (an emphasis on health science would be a plus) or demonstrated proficiency through Regulatory Affairs Certification (RAC).
- Position acts independently to determine methods and procedures on new assignments.
- Job requires extensive knowledge and many years of experience, with the incumbent often reviewed as the most knowledgeable person on this subject in the company.
- Ability to read, understand and interpret medical device, FDA and EU regulations and requirements.
- Excellent communication skills required, written and verbal. Write procedures; perform presentations to staff and management.
- Position presents training to all employees on U.S. FDA Quality System regulations, ISO 13485, and updates management on new regulatory issues.
- Expertise in personal computer application software, such as word-processing, Excel and Access.
- Ability to read, understand and interpret contractual agreements, patents, legal documents, advance technical articles and professional scientific and dental journals.

OTHER REQUIREMENTS

1. Creative problem solving skills for regulatory strategies.
2. Originality and creativity in making presentations of FDA and QSR regulations so that they are interesting and can be understood on all levels.
3. Ability to enroll others in quality and compliance initiative.