TITLE: Quality Manager

DEPARTMENT: Rehabilitation

REPORTS TO: General Manager

BENEFITS: Medical, dental, vision, life insurance, short and long term disability insurance, paid time off package, 401k with company contribution, FSA or HSA options, educational assistance, dependent scholarship program, onsite fitness center, and much more!

General Responsibilities:

The appointed Management Representative for the company ensuring that processes needed for the Quality Management System (QMS) are established, implemented and maintained. This position reports to top management on the performance of the QMS and any need for improvement. The Quality Manager is the liaison with the external regulatory and assessment bodies on all matters related to the external establishment, registration, compliance and accreditation processes. Responsible for the development, implementation and administration of organization activities, policies and procedures to support and ensure regulatory compliance. Core team member supporting cross-functional teams with guidance to maintain compliance with US and appropriate international regulatory requirements. Uses a thorough understanding of regulatory post-market obligations for the US FDA and international post-market regulatory requirements to direct activities that ensure compliance.

Specific Duties:

- Responsible for the day-to-day oversight and management of the Quality Management System and assigned projects. Serves as the primary regulatory resource for the organization
- Understands and interprets U.S. and international medical device regulatory requirements, provides interpretive guidance on requirements to all affected departments, especially product development, software engineering, IT, production, service & installation, sales & marketing teams
- Provides regulatory risk assessments and options to appropriate teams and management
- Manages regulatory compliance, evaluates regulatory issues and provides accurate and timely recommendations and alternatives, as needed, to management and functional business departments
- Interact effectively with functional business departments in order to coordinate and facilitate documentation requirements, ensuring that timelines are met and files are comprehensive
- Develops and maintains procedures and policies to ensure ongoing compliance of existing and new products
- Supports the Quality Audit system by participating and leading internal audits
- Compile and maintain appropriate Quality Management System files
- Provide leadership and direction to assigned resources. Provide timely and appropriate performance feedback
- Supports New Product Development projects
- Manages the Corrective and Preventive Action (CAPA) system
- Develop Quality Metrics and coordinate quality data collection and analyses for Management Reviews
- Responsible maintaining FDA Class I exempt Registration and Listing
- Act as direct liaison with FDA as needed, including escorting government inspectors during inspections and providing post-inspection follow-up information as requested
- Analyze product complaints and make recommendations regarding their reportability
- Independently review and approve relevant documents, including engineering changes, advertising and promotional materials and product development reports
- Maintain current knowledge base of existing and emerging regulations, standards, or guidance documents
- Interpret regulatory rules or rule changes and ensure implementation through corporate policies and procedures
- Prepare or maintain technical files as necessary to obtain and sustain product approval
- Serves as primary Gorbel interface with regulatory agencies
- Other duties as assigned

Job Qualifications:

- Possess a minimum 5 years medical device regulatory and compliance experience
- Experience in effective interdepartmental interaction as a regulatory affairs SME
- FDA Class I and Class II regulatory experience, (21 CFR, Part 820)
- Experience with international regulations, particularly ISO 13485
- Demonstrated experience in project management and FDA medical device documentation
- Demonstrated ability to work effectively in a highly charged, fluid environment
- Demonstrated ability to independently manage multiple projects
- Post-market medical device surveillance experience
- Very detail-oriented, well-organized and driven to meet deadlines and program goals
- Strong verbal and written communication skills, including the ability to make effective and persuasive presentations
- Good computer skills with proficiency in Microsoft Office
- Ability to compile data and summarize results
- Bachelor's degree
- Demonstrated working knowledge of engineering principles preferred
- Compliance Project Leader from inception to launch of medical device preferred
- International product launch preferred

To apply for this position, please complete an employment application and send to careers@gorbel.com.

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