JOB DESCRIPTION

Job Title: Regulatory Affairs Director (Martech Facility)
Department: Regulatory Affairs
Reports To: President
FLSA Status: Exempt
Prepared By: Human Resources
Prepared Date: 11APR2019
Approved By:
Approved Date:

Summary: Oversees and manages the regulation process for products requiring governmental or Notified Body approval/clearance, including filing necessary applications and handling all interactions with the FDA, Notified Body (CE Marking) and Health Canada. Coordinates the accumulation of technical information and creates submissions for medical devices for approval or clearance in (FDA) and Canadian markets and to be CE Marked by performing the following duties:

Essential Duties and Responsibilities include the following. Other duties may be assigned.

- Manage Regulatory Affairs, NA and EU staff members by assigning workload.
- Works closely with HR handling interviews, hiring, discipline, and reviews.
- Responsible to manage staff members PTO and timesheets.
- Act as mentor/leader to staff members.
- Train and/or construct training plans for Regulatory Affairs, NA and EU and Product Support staff members for Personnel Development.
- Create 510(k), IDE, and PMA submissions for Domestic Market (FDA)
- Submit Q-Submission Meetings, such as pre-submission and issue

meetings, to the FDA as needed.

- Create Technical Files and Design Dossiers for submission to the designated Notified Body to obtain CE Marking.
- Create Technical Files and Design Dossiers Amendments for currently approved product lines to be submitted to the designated Notified Body (CE Marking)
- Notify the designated Notified Body of any significant changes regarding product changes (not including supplier management changes)
- Review and Maintain Technical Files and Design Dossier after receiving CE Marking.
- Perform routine reviews of technical files and design dossiers when required.
- Submit CE Marked product for periodic audits and recertification as necessary.
- Create New License Submissions, Amendments, and Fax Back applications for Health Canada.
- Create and maintain Technical Files and Design Dossiers for CE Marking (EU).
- Respond to questions from FDA, Health Canada, and designated Notified Body during review and approval process for submissions.
- Organize and file all submissions and correspondences with the FDA, Health Canada, and designated Notified Body.
- Notify Health Canada of any significant changes regarding product changes (not including supplier management changes)

JOB DESCRIPTION

- Store all clearance and approval documentation from the FDA, Health Canada, and the designate Notified Body.
- Create, review, and store all internal documentation for approved or cleared product lines.
- Work in partnership with Product Support to maintain and update Technical Files and Design Dossiers.
- Oversee Product Support and help manage and prioritize work load.
- Work in partnership with other team members, management, sales, product management, project management, compliance, quality and engineering to complete regulatory submissions and product management meetings
- Support and assist with the external audit program and participate in inspections and audits by FDA, Health Canada, and designated Notified Body.
- Host internal audit of the Regulatory Department.
- Review all internal and external regulatory findings.
- Complete or assign all Corrective and Preventive Actions generated from audit findings.
- Develop and maintain policies and procedures regarding to regulatory submissions and processes.
- Review regulatory publications, standards, and guidances to keep appraised of new regulatory developments.
- Support regulatory responsibilities during audits by domestic,

Canadian, or European customers.

- Communicate with staff and management effectively.
- Handle special assignments as required.
- Review change requests for approved products.
- Review internal and external variances.
- Work in partnership with Compliance and QA/QC in designing and enhancing quality management systems to facilitate overall regulatory compliance.
- Review and respond to regulatory requests, such as providing 510(k) clearances to customers, etc.
- Organize, review and coordinate required technical testing for submissions. Review 10993 biological endpoints and biological evaluation plans, as needed.
- Coordinate with testing facilities to support submissions and testing requirements.
- Attend or lead regulatory meetings.

Supervisory Responsibilities

Directly supervises Regulatory Associates. Carries out supervisory responsibilities in accordance with the organization's policies and applicable laws. Responsibilities include interviewing, hiring, and training employees; planning, assigning, and directing work; appraising performance; rewarding and disciplining employees; addressing complaints and resolving problems.

JOB DESCRIPTION

Competencies

To perform the job successfully, an individual should demonstrate the following competencies:

Analytical - Synthesizes complex or diverse information; Collects and researches data; Uses intuition and experience to complement data.

Design - Generates creative solutions; Demonstrates attention to detail.

Problem Solving - Identifies and resolves problems in a timely manner; Gathers and analyzes information skillfully; Develops alternative solutions; Works well in group problem solving situations; Uses reason even when dealing with emotional topics.

Project Management - Coordinates projects; Communicates changes and progress.

Technical Skills - Assesses own strengths and weaknesses; Pursues training and development opportunities; Strives to continuously build knowledge and skills; Shares expertise with others.

Customer Service - Manages difficult or emotional situations; Responds promptly to customer needs; Solicits customer feedback to improve service; Responds to requests for service and assistance; Meets commitments.

Interpersonal Skills - Focuses on solving conflict, not blaming; Maintains confidentiality; Listens to others without interrupting; Keeps emotions under control; Remains open to others' ideas and tries new things.

Oral Communication - Speaks clearly and persuasively in positive or negative situations; listens and gets clarification; Responds well to questions; Demonstrates group presentation skills; Participates in meetings.

Written Communication - Writes clearly and informatively; Edits work for spelling and grammar; Varies writing style to meet needs; Presents numerical data effectively; Able to read and interpret written information.

Teamwork - Balances team and individual responsibilities; Exhibits objectivity and openness to others' views; Gives and welcomes feedback; Contributes to building a

positive team spirit; Puts success of team above own interests; Able to build morale and group commitments to goals and objectives; Supports everyone's efforts to succeed.

Visionary Leadership - Displays passion and optimism; Inspires respect and trust.

Change Management - Communicates changes effectively; Builds commitment and overcomes resistance.

Leadership - Exhibits confidence in self and others; Inspires and motivates others to perform well; effectively influences actions and opinions of others; Accepts feedback from others; Gives appropriate recognition to others.

Managing People - Includes staff in planning, decision-making, facilitating and process improvement; Takes responsibility for subordinates' activities; Makes self-available to staff; Provides regular performance feedback; Develops subordinates' skills and encourages growth; Solicits and applies customer feedback (internal and external); Fosters quality focus in others; Improves processes, products and services.; Continually works to improve supervisory skills.

Delegation - Delegates work assignments; Matches the responsibility to the person; Gives authority to work independently; Sets expectations and monitors delegated activities; Provides recognition for results.

Quality Management - Looks for ways to improve and promote quality; Demonstrates accuracy and thoroughness.

Diversity - Shows respect and sensitivity for cultural differences; promotes a harassment-free environment.

Ethics - Treats people with respect; Keeps commitments; Inspires the trust of others; Works with integrity and ethically; Upholds organizational values.

Organizational Support - Follows policies and procedures; Completes administrative tasks correctly and on time; supports organization's goals and values.

Strategic Thinking - Adapts strategy to changing conditions.

Judgement - Displays willingness to make decisions; Exhibits sound and accurate

judgment; Supports and explains reasoning for decisions; Includes appropriate people in decision-making process; Makes timely decisions.

Motivation - Sets and achieves challenging goals; Demonstrates persistence and overcomes obstacles; Measures self against standard of excellence.

Planning/Organizing - Prioritizes and plans work activities; Uses time efficiently; Plans for additional resources; Sets goals and objectives; Develops realistic action plans.

Professionalism - Approaches others in a tactful manner; Reacts well under pressure; Treats others with respect and consideration regardless of their status or position; Accepts responsibility for own actions; Follows through on commitments.

Quality - Demonstrates accuracy and thoroughness; Looks for ways to improve and promote quality; Applies feedback to improve performance; Monitors own work to ensure quality.

Quantity - Meets productivity standards; Completes work in timely manner; Strives to increase productivity; Works quickly.

Safety and Security - Observes safety and security procedures; Reports potentially unsafe conditions; Uses equipment and materials properly.

Adaptability - Adapts to changes in the work environment; Manages competing demands; Changes approach or method to best fit the situation; Able to deal with frequent change, delays, or unexpected events.

Attendance/Punctuality - Is consistently at work and on time; Ensures work responsibilities are covered when absent; Arrives at meetings and appointments on time.

Dependability - Follows instructions, responds to management direction; Takes responsibility for own actions; Keeps commitments; Commits to long hours of work when necessary to reach goals; Completes tasks on time or notifies appropriate person with an alternate plan.

Initiative - Volunteers readily; Undertakes self-development activities; Seeks increased responsibilities; Looks for and takes advantage of opportunities; Asks for and offers help

when needed.

Innovation - Displays original thinking and creativity; Meets challenges with resourcefulness; Generates suggestions for improving work; Develops innovative approaches and ideas; Presents ideas and information in a manner that gets others' attention.

Qualifications To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and/or Experience

Bachelor's degree (B. A./B.S.) from four-year college or university; or three to five years related experience and/or training; or equivalent combination of education and experience.

Language Skills

Ability to read, analyze, and interpret common scientific and technical journals, financial reports, and legal documents. Ability to respond to common inquiries or complaints from customers, regulatory agencies, or members of the business community. Ability to write speeches and articles for publication that conform to prescribed style and format. Ability to effectively present information to top management, public groups, and/or boards of directors.

Mathematical Skills

Ability to apply advanced mathematical and statistical concepts. . Ability to apply mathematical operations to such tasks as frequency distribution, determination of test reliability and validity, analysis of variance, correlation techniques, sampling theory, and factor analysis.

Reasoning Ability

Ability to define problems, collect data, establish facts, and draw valid conclusions. Ability to interpret an extensive variety of technical instructions in mathematical or

diagram form and deal with several abstract and concrete variables.

Computer Skills

To perform this job successfully, an individual should have knowledge of Database software; Internet software; Inventory software; Manufacturing software; Spreadsheet software and Word Processing software.

Certificates, Licenses, Registrations

ASQ certification is preferred.
RAC certification is preferred.

Other Skills and Abilities

Knowledge of Lean Manufacturing and Six Sigma are preferred.

Other Qualifications

Availability to travel both domestically and internationally if the need arises.

Physical Demands The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this Job, the employee is regularly required to sit; use hands to finger, handle, or feel; talk or hear and taste or smell. The employee is occasionally required to stand and walk. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, distance vision, color vision, peripheral vision, depth perception and ability to adjust focus.

Work Environment The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

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While performing the duties of this Job, the employee is occasionally exposed to moving mechanical parts. The noise level in the work environment is usually quiet to moderate.