



Job Description

Job Title:	Regulatory Affairs Specialist		
Job Code:		FLSA:	Salaried Exempt
Department:	Regulatory		
Reports To:	Director of Regulatory Affairs/ Chief Operating Officer		

Job Scope and Quality Impact:

This position is responsible for providing guidance on regulatory requirements as well as assisting in regulatory related projects and tasks ensuring compliance with FDA regulations, ISO standards, and other regulatory agencies.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential job task satisfactorily. The tasks 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.

- Provides guidance on regulatory requirements necessary for strategic and contingency planning, including developing regulatory strategic plans to teams for solutions.
- Represents regulatory affairs on product development and commercialization teams.
- Ensures compliance with standards and execution of corrective actions and is the liaison with domestic and international customers and vendors.
- Prepares and oversees documentation packages for submission to global regulatory agencies. Tracks timelines and documents milestone achievements for inclusion in regulatory submissions. Interacts with regulatory agencies as part of submission review and on-site audit support (e.g. IDEs, PMAs, annual reports, 510(k)s, STEDs, and CE marking design dossiers and technical files).
- Assists with customer complaints/CAPA system.
- Develops risk assessment review process for all marketed devices and implementation of changes to risk management process as needed.
- Monitors proposed and current US and EU regulations and guidance and advises on the impact of such regulations.
- Reviews documents for regulatory claims, promotional material, labeling content, product and process changes, and product documentation.
- Collaborates and takes direction from RA management.

Projects and Other Duties:

- Perform other duties as assigned.

Position Qualifications

- Strong working knowledge of US and EU regulations that affect Class III medical devices.
- Experience working on cross functional projects.
- Fluent English with strong written and verbal communication skills.
- Excellent analytical thinking and problem-solving skills.

Minimum Education:

- Bachelor's degree in a related field, a scientific degree is preferred.

Minimum Experience:

- 3 years of experience in a regulatory role or related area.

Specific Skills, Knowledge & Behaviors

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

Core Competencies:

- **Interpersonal Effectiveness:** Actively seeks to understand perspectives and interpersonal needs and expectations of others at all levels, builds self-awareness, flexes personal style appropriately, and works through conflicts constructively and appropriately
- **Communication:** Effectively uses all mediums of communication as appropriate, presents well to groups, actively listens, and continuously identifies opportunities to build communication skills
- **Collaboration & Teamwork:** Actively works together with formal and informal team members to build relationships and achieve team goals
- **Prioritization:** Effectively prioritizes work to ensure timely completion of work within scope
- **Technical Expertise:** Continuously builds functional and technical expertise, and pro-actively applies that technical expertise in progressively broader scope
- **Continuous Improvement:** Learns and uses best practices tools and methodologies to assess, identify, and executes on opportunities to improve; Focus on learning and building new capabilities into self
- **Problem Solving & Problem Prevention:** Learns and uses strong problem solving methodologies and tools, focuses on root cause analysis, and shows orientation towards problem prevention
- **Accountability:** Focuses on results, takes initiative without direction, takes ownership for all work within scope, builds relationships and works across departments, functions, or areas of responsibility

Equipment Use & Abilities Required:

- **Equipment Use:** Copy machines, fax machines, calculators and personal computers and computer terminals.
- **Computer Skills:** Software proficiency in Microsoft Office Suite.
- **Language Skills:** Ability to read, analyze, and interpret general business periodicals, professional journals, technical procedures, legal documents or governmental regulations. Ability to write reports, business correspondence, and procedure manuals. Ability to effectively present information and respond to questions from groups of managers, clients, customers, and the general public.
- **Mathematical Skills:** Ability to work with mathematical concepts such as probability and statistical inference. Ability to apply concepts such as fractions, percentages, ratios, and proportions to practical situations.
- **Reasoning Ability:** Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram, or schedule form

WORK ENVIRONMENT & PHYSICAL DEMANDS OF THE JOB:

The noise level in the work environment is usually quiet. While performing the duties of this job, the employee is regularly required to sit; use hands and fingers; talk or hear. The employee is occasionally required to reach with hands and arms and to move within and between the buildings. A computer terminal is used to access, input, and retrieve data. The employee must occasionally lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision.

Acknowledge Receipt:

Employee Printed Name

Signature

Date

Manager Printed Name

Signature

Date