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POSITION OVERVIEW

Job Title:	Regulatory Affairs Manager
Business Title:	*Regulatory Affairs Manager*
Job Code:	REGADDMGR
FLSA Status:	Exempt
Department:	Legal
Reports to:	VP, Managing General Counsel, Regulatory
Location:	Remote, USA or Edina, MN
Draft Date:	March 9, 2026
Revision Date:	N/A
Approved By:	Kate O'Connor
Role:	Individual Contributor

POSITION SUMMARY

The *Regulatory Affairs Manager* is responsible for regulatory affairs relating to investigatory and cleared software as a medical device (SaMD) products, and supporting regulatory compliance in other areas on an as-needed basis. The *Regulatory Affairs Manager* is responsible for maintaining an electronic Quality Management System; monitoring FDA guidance and other regulations, communicating how they impact the company; assisting software engineering and development teams with compliance requirements; drafting or contributing to FDA submissions such as pre-submission requests and 510(k) applications, reports, registrations, UDI maintenance and other activities applicable to medical device regulation, guidance, and standards.

POSITION DUTIES AND RESPONSIBILITIES

- Maintain QMS to remain in compliance with applicable laws and regulations
- Hold regular meetings with appropriate team members as required by QMS, including executive management
- Assist with building and maintain Design History Files for FDA SaMDs
- Compile and file 510(k) pre-submissions, 510(k) submissions and De Novo submissions in consultation with legal counsel when needed
- Perform quality checks on QMS and SaMD Design History Files
- Work with vRad leadership, including Director of Software Engineering, CIO, CEO, and others to make critical decisions such as regulatory pathways and regulatory strategies
- Assess device related incidents/complaints for medical device reporting requirements
- Compile and submit reportable events to relevant regulatory bodies
- Manage recalls and field actions, support CAPA completion
- Review and create device labelling
- Support internal and external regulatory audits
- Support expansion into global medical device markets
- Participate on Research Advisory Committee
- Up to 10% travel as needed
- Other duties as assigned

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KNOWLEDGE, SKILLS, AND ABILITIES

- Science fluency must be able to digest complex data while keeping the big picture through good analytical skills; firm understanding of statistics is desirable
- Excellent written and verbal communication skills with the ability to listen, articulate, synthesize and advocate
- Proactive, high performance, result oriented and manage projects with ethical integrity
- Technical system skills (e.g. MS office applications, databases, efficient online research).
- Manage multiple projects and deadlines
- Ability to identify compliance risks and escalate when necessary
- Demonstrate both creative and critical thinking skills

REQUIRED QUALIFICATIONS

- Bachelor's degree or country equivalent in Engineering or Science or related scientific discipline, or equivalent. Higher degree/PhD will be an advantage
- Minimum 3-5 years regulatory or equivalent experience within a device or pharmaceutical company, clinical research organization, or similar organization

PREFERRED PROFESSIONAL SKILLS AND EXPERIENCE

- Experience with eSTAR, SaMD, and eQMS
- Experience with cyber security frameworks and enterprise risk management concepts

Physical Activities

Ascending or descending ladders, stairs, scaffolding, ramps, poles and the like.

☒ Never ☐ Occasionally ☐ Constantly

Moving self in different positions to accomplish tasks in various environments including tight and confined spaces.

☒ Never ☐ Occasionally ☐ Constantly

Remaining in a stationary position, often standing or sitting for prolonged periods.

☐Never ☐ Occasionally ☒ Constantly

Moving about to accomplish tasks or moving from one worksite to another.

☐ Never ☒ Occasionally ☐ Constantly

Adjusting or moving objects up to 15 pounds in all directions.

☐ Never ☒ Occasionally ☐ Constantly

Communicating with others to exchange information.

☐ Never ☐ Occasionally ☒ Constantly

Repeating motions that may include the wrists, hands and/or fingers.

☐ Never ☐ Occasionally ☒ Constantly

Operating machinery and/or power tools.

☒ Never ☐ Occasionally ☐ Constantly

Operating motor vehicles or heavy equipment.

☐ Never ☒ Occasionally ☐ Constantly

Assessing the accuracy, neatness and thoroughness of the work assigned.
☐ Never ☐ Occasionally ☒ Constantly

Environmental Conditions

Low temperatures.
☐ Never ☒ Occasionally ☐ Constantly
High temperatures.
☐ Never ☒ Occasionally ☐ Constantly
Outdoor elements such as precipitation and wind.
☐ Never ☒ Occasionally ☐ Constantly
Noisy environments.
☒ Never ☐ Occasionally ☐ Constantly
Hazardous conditions.
☒ Never ☐ Occasionally ☐ Constantly
Poor ventilation.
☒ Never ☐ Occasionally ☐ Constantly
Small and/or enclosed spaces.
☒ Never ☐ Occasionally ☐ Constantly
No adverse environmental conditions expected.
☐ Never ☒ Occasionally ☐ Constantly

Physical Demands

Sedentary work that primarily involves sitting/standing.
☐ Never ☐ Occasionally ☒ Constantly
Light work that includes moving objects up to 20 pounds.
☐ Never ☒ Occasionally ☐ Constantly
Medium work that includes moving objects up to 50 pounds.
☒ Never ☐ Occasionally ☐ Constantly
Heavy work that includes moving objects up to 100 pounds or more.
☒ Never ☐ Occasionally ☐ Constantly

I have reviewed this job description and I understand all my job duties and responsibilities. I am able to perform the essential functions as outlined. If I have any questions about job duties not specified on this description that I am asked to perform, I should discuss them with my manager or a member of the Human Resources team.

I acknowledge that the job has been explained to me both verbally and in written format.

_____ _____
Support Teammate's Signature Date