



901 Deming Way, Suite 302, Madison, WI 53717 | [www.OnLume.com](http://www.OnLume.com)

## **Regulatory Affairs and Quality Assurance Specialist**

OnLume Surgical is creating the future of medical imaging devices for image-guided surgery. We are seeking a highly motivated, creative, and task oriented regulatory affairs and quality assurance specialist.

### **Position Summary:**

This is a hands-on, task oriented, position that involves a variety of assignments in both regulatory affairs and quality assurance at an early-stage medical equipment manufacturer.

### **Responsibilities and Duties Include:**

- Function as both a quality assurance and regulatory affairs subject matter expert on OnLume Surgical product development teams. Assure product development activities comply with quality management system processes and applicable statutory regulations.
- Regularly audit and report the status of the organization compliance with quality management system requirements. Initiate and track corrective and/or preventive actions projects to address non-compliance and maintain compliance with applicable statutory requirements.
- Participate in management review of the quality management system.
- Prepare responses to regulatory authorities' inquiries.
- Stay abreast of quality and regulatory procedures, guidance documents, standards, and changes in regulatory climate.
- Author regulatory filings and issue internal reports (e.g., 510(k), IDE, etc.) in support of OnLume Surgical's commercial and scientific goals and objectives.
- Process product complaints and customer feedback per quality management system processes.
- Additional responsibilities and duties will be assigned as necessary to grow the business and to assure compliance with applicable statutory regulations.

### **Competency Requirements Include:**

- 5+ years of experience as a regulatory affairs or quality management system specialist at a medical electrical equipment manufacturer. RAC and ASQ certifications are a major plus.
- Demonstrated success at clear communication, problem-solving, and interpersonal skills with both internal and external stakeholders.
- Excellent written and verbal communication skills with the ability to listen, articulate, 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)
- Ability to manage multiple projects and deadlines
- Ability to identify compliance risks and escalate when necessary
- Demonstrate both creative and critical thinking skills
- Educational requirements: Bachelor's degree in a scientific or engineering curriculum. Advanced degree is a plus.



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**Other Employment Details:**

**Benefits:**

- Benefits include medical, dental, vision, life, short and long term disability insurance, PTO, and paid holidays.

**Job Type:**

- Full-time

**Location:**

- OnLume home office in Madison Wisconsin. Travel as necessary to fulfill responsibilities and duties.
- COVID-19 considerations: Remote work is temporarily optional due to COVID-19.

**EEO/AAP Statement:**

OnLume Inc. is an EEO/AAP employer; all business decisions (employment, promotions, compensation, etc.) are made without regard to race, color, religion, creed, gender, national origin, age, disability, marital or veteran status, sexual orientation, gender identity, national origin, or any other legally protected status.