SHURIG SOLUTIONS INC.

JOB DESCRIPTION

JOB TITLE	**Director of Regulatory Affairs Specialist/Manager**
DEPARTMENT	**Regulatory Affairs**
FLSA	**Exempt**
SALARY GRADE	
REPORTS TO	**Vice President of Operations**
SUPERVISES	**N/A**
LAST REVISED	**January 2022**

SpectralMD *Seeing the Unknown*

Position Summary:

The Director of Regulatory Affairs will be responsible for driving the Regulatory Strategy and the preparation of regulatory submissions required to market or investigate new or modified medical devices in both domestic and international markets. This responsibility entails supporting the development, execution and management of procedures and systems are designed to ensure that the product development process, including clinical studies, addresses all regulatory requirements as well as the objectives of the business.

Supervisory Responsibilities:

- None

Essential Duties and Responsibilities:

- Understands and interprets U.S. and international medical device regulatory requirements.
- Develops strategies for submissions to FDA and other regulatory agencies.
- Assesses and communicates regulatory risks and provides options.
- Provides regulatory opinions on premarket regulatory requirements, export, and labeling requirement
- Provides guidance on requirements to product development teams.
- Prepares appropriate U.S. regulatory submissions necessary for marketing authorization including: 510(k)s, De Novo, Premarket Approval Applications (PMA) and supplements; Product Development Protocols (PDP); Investigational Device Exemptions (IDE); Pre-Submissions (Q-subs).
- Prepares and/or maintains on-going registration and/or licensure activities for products for export.
- Interacts and negotiates with U.S. regulatory and other applicable government agencies.
- Prepares and/or coordinates the preparation of data/information requested by regulatory agencies and provides appropriate responses to all such requests.
- Participates in the development and review of product release documents under document control.
- Reviews clinical protocols to assure collection of appropriate data for regulatory submissions.
- Periodically monitors status of clinical studies and reviews resultant clinical study data. Based on these data and considering the regulatory requirements, recommends appropriate courses of action.
- Reviews labels, labeling, and promotional material content for compliance with applicable regulations and policies.
- Assists with the creation of technical files, essential requirements checklists, clinical investigation applications, and CE Marking.

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Qualifications:

Required education and experience:

- Ideal candidate will have the ability to understand and interpret U.S. and international medical device regulatory requirements.
- Bachelor's degree required, strongly preferred in the biomedical engineering, biology, chemistry or related science.
- Minimum 8 years' experience in the device/diagnostic industry, preferably in the area of regulatory affairs. Preference given to experience with medical device software applications.

Knowledge, Skills and Abilities:

- Current knowledge of U.S. medical device regulatory requirements, Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) and Quality System Regulations (QSR); current knowledge of European Medical Device and IVD Directive requirements and European quality system standards a plus.
- Ability to effectively communicate both verbally and in writing to all levels within the organization and external to the organization.
- Experience with the MDD and familiar with the MDR.
- Experience working with Notified Bodies.
- Excellent verbal and written communication skills.
- Excellent organizational skills and attention to detail.
- Excellent time management skills with a proven ability to meet deadlines. Project management experience desirable.
- Proficient with Microsoft Office Suite or related software.

Physical Requirements:

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

- Prolonged periods of sitting at a desk and working on a computer.
- Must be able to lift up to 15 pounds at times.

Travel:

Up to 10% of travel time expected for the position

Equal Employment Opportunity:

Spectral MD, Inc. is an equal opportunity and affirmative action employer. All applicants will be considered for employment without regard to race, color, ancestry, national origin, sex, gender, sexual orientation, marital status, religion, age, disability, gender identity, results of genetic testing, protected veteran status, or any other characteristic protected by applicable federal, state or local laws.

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Acknowledgement:

I have read and understand my job description, along with the physical requirements for the job. I understand that other duties and tasks may be assigned as necessary. A signed copy of this job description will be placed in my personnel file.

Please note this position description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this position. Duties, responsibilities and activities may change at any time with or without notice.

I also understand that this job description does not constitute a contract of employment nor alter my status as an at-will employee. I have the right to terminate my employment at any time and for any reason, and the employer has a similar right.

_____	_____	_____
Team Member's Name	**Team Member's Signature**	**Date**