gSource®

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Job Description

Job Title:	Regulatory Affairs Specialist
Job Summary:	Responsible for coordinating the workflow of the team and the collection of technical information by either preparing or leading the preparation of submissions for medical devices to various governmental regulatory agencies and maintaining current revisions of control documents.
Wage Category:	RAS I, II, III
Department:	Quality
Reporting to:	Quality Manager
FLSA Status:	Exempt (Fair Labor Standards Act)

Responsibilities of essential functions include:

1. Appointed as Person Responsible for Regulatory Compliance (PRRC)
2. Leads the preparation, submission and maintenance of regulatory filing documents with the appropriate local, state and federal agencies
3. Prepare FDA submissions and CE Mark Technical Documentation File, including 510(k) submissions, Device Master Files, technical files and post market surveillance for product changes and/or new products as required to ensure timely clearance or approvals
4. Create and maintain regulatory submission timeliness and track deliverables to ensure company goals are met
5. Develop and communicate recommendations regarding new/emerging regulations to management and project teams
6. Represent the company and work directly with regulatory authorities on regulatory issues and submissions
7. Participate in cross-functional departmental meetings and discussions, provide input regarding regulatory strategy
8. Support to international customers regarding regulatory, import and/or export requirements and/or requests
9. Provide support in regulatory inspection or regulatory audits by any regulatory agency or customer audit
10. Adhere strictly to all CGMP, FDA, ISO, EU and company procedures to ensure the quality and integrity of the products and safety of the workplace
11. Responsible for document control
12. Responsible for the revision, distribution and maintenance of controlled documents including Standard Operating Procedures, Work Instructions, Forms, specifications and other miscellaneous documents
13. Responsible for maintaining controlled document libraries
14. Prepare controlled documents through the change control process including editing, proofreading, tracking, copying, distributing, scanning and filing

Responsibilities of non-essential functions include:

15. Maintain commitment to Quality Goals and Quality Policy
16. Complete jobs and tasks as assigned
17. Working Schedule: 8:30 am to 5:15 pm

Employee: _____ _____ _____
Last Name First Name Initial

Nothing in this job description restricts management's right to assign or reassign responsibilities to this position at any time.

Signatures:

_____ _____/_____/_____
Employee mm dd yy

_____ _____/_____/_____
Manager/Supervisor mm dd yy