



## Manager of Regulatory Affairs

The Manager of Regulatory Affairs is the global Regulatory Lead for IntriCon. The Manager of Regulatory Affairs will develop and execute regulatory strategy and plans for complex projects including product enhancement and maintenance of licenses/authorizations for existing marketing authorizations. Will develop and document sound regulatory decisions and justifications in order to comply with ISO 13485, the Quality System Regulations (QSR) of the FDA, and EU MDD/MDR. Leads the RA function on assigned cross-functional project teams and establishes appropriate communication within RA and other functions primarily at project level. Supports and complies with various global regulatory bodies in accordance with specific foreign countries' requirements. Ensures project teams and business objectives and deliverables are aligned with regulatory strategy. Monitors applicable regulatory requirements and assures compliance. May be required to perform all or a combination of the following:

- Ensure that all released products meet the relevant regulatory requirements, including FDA, EU, JPAL, etc.
- Coordinate/manage all correspondence between IntriCon and Notified Body.
- Manage all Notified Body, FDA, FAA, and corporate audits.
- Interpret all new standards that are applicable to IntriCon's quality system, evaluate the potential impact on business and communicate changes to management.
- Maintain all applicable standards.
- Work with all internal functional departments to ensure IntriCon product compliance with all relevant quality system requirements and standards.
- Coordinate with R&D and Manufacturing Engineering to ensure compliance to required standards related to all new project development, testing and manufacturing.
- Coordinate with customers, Sales, & Marketing to define relevant standards as early as possible in product, project, and platform planning
- Manage and maintain all communication with IntriCon authorized representative.
- Manage International product registrations and license applications.
- Prepares, manages, and maintains technical summary files and STEDs demonstrating compliance with MDD/MDR and FDA expectations
- Responsible for corporate environmental compliance activities such as RoHS, REACH, Conflict Minerals, and California Proposition 65
- Manage calibration activity for Minnesota facilities
- Continually seeks regulatory process and procedure improvements as appropriate.
- Plans and manages regulatory compliance activities in accordance with agreed budgets and timescales.
- Establish, implement and manage necessary communication strategy for the awareness and improvement of regulatory compliance issues across all departments.
- May travel as required among IntriCon facilities, approximately 10 nights per year.
- Other duties may be assigned.

**Qualifications:**

- Bachelor's degree (B. S.) from four-year college or university in science or a technical area; or equivalent experience. Master's degree preferred.
- Five to seven (5-7) years' experience in regulatory compliance in a medical device regulated environment.
- Strong working knowledge of regulatory requirements for European Community, Canada and other countries, as well as knowledge of ISO 13485, QSR, and MDD/MDR.
- Excellent communication skills, both written and oral.
- Ability to review and evaluate scientific and technical data.
- Ability to work effectively with other functional departments to be able to provide solutions, rather than just present the problems.
- Excellent computer skills – Excel, Word, PowerPoint.
- Ability to communicate outside the organization, representing IntriCon to customers, the public, government and other external sources.
- Knowledge of principles and processes involved in business and organizational planning, coordination and execution.

**Benefits of Employment**

We offer our full-time employees a full benefits package that includes: Vacation, Holiday Pay, Medical, Dental, Life, 401(k), Employee Stock Purchase Program (ESPP), Short and Long-Term Disability and Flexible Benefit Plan.

IntriCon is an Equal Opportunity Employer.

Job Type: Full-time

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