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| **Job Title:** | Senior Regulatory Affairs Specialist |
| **Reports To:** | Director, Regulatory Affairs |
| **Location:** | 900 Long Lake Road, New Brighton, MN 55112 |
| **Date:** | 2017 July 12 |

**Purpose/Role**

*A brief description of the primary responsibilities for which the employee is accountable*

The Senior Regulatory Affairs Specialist completes projects as assigned to obtain international regulatory approvals and ensures corporate compliance to the applicable rules and regulations.

**Position Description**

*A listing of the deliverables to be accomplished, including specific duties/activities that make up the job*

Prepare regulatory submissions, including:
- Design dossiers, technical files, 510(k)s, PMAs and IDEs
- Significant change assessments
- Annual renewals, registrations and listings
- Other submissions as required

Perform other regulatory tasks as required, including:
- Ensuring labeling meets requirements
- Carrying out vigilance reporting and product recalls
- Supporting quality systems
- Assessing complaints
- Writing and maintaining procedures for regulatory operations
- Supporting preclinical and clinical trials
- Performing risk analyses
- Preparing reports and literature searches

Maintain awareness of applicable laws and regulations

Help promote awareness of regulatory requirements throughout the organization

Assist the Director of Regulatory Affairs as required

**Qualifications**

*Represents the desired qualifications but may not reflect the employee's existing qualifications*

**Education:**

Bachelor's degree in a Scientific discipline or equivalent

**Experience:**

Previous regulatory experience (5+ years) required

Regulatory Affairs Certification an asset

**Skills:**

Knowledge of relevant international regulations and standards related to medical devices

Excellent verbal and written communication skills

*The purpose of this description is to provide a concise statement of the major responsibilities of this position in a standardized format. It is not intended to describe all the elements of the work that may be performed and should not serve as the sole criteria for personnel decisions and action.*

**Approvals:**

_____ _____

Employee (signature) Date

_____ _____

Manager (signature) Date