

	Document Title: Job Description		
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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

<p>Purpose/Role <i>A brief description of the primary responsibilities for which the employee is accountable</i></p> <p>The Senior Regulatory Affairs Specialist completes projects as assigned to obtain international regulatory approvals and ensures corporate compliance to the applicable rules and regulations.</p>
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<p>Position Description <i>A listing of the deliverables to be accomplished, including specific duties/activities that make up the job</i></p> <p>Prepare regulatory submissions, including:</p> <ul style="list-style-type: none"> • Design dossiers, technical files, 510(k)s, PMAs and IDEs • Significant change assessments • Annual renewals, registrations and listings • Other submissions as required <p>Perform other regulatory tasks as required, including:</p> <ul style="list-style-type: none"> • 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 <p>Maintain awareness of applicable laws and regulations Help promote awareness of regulatory requirements throughout the organization Assist the Director of Regulatory Affairs as required</p>
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<p>Qualifications <i>Represents the desired qualifications but may not reflect the employee's existing qualifications</i></p> <p>Education: Bachelor's degree in a Scientific discipline or equivalent</p> <p>Experience: Previous regulatory experience (5+ years) required Regulatory Affairs Certification an asset</p> <p>Skills: Knowledge of relevant international regulations and standards related to medical devices Excellent verbal and written communication skills</p>
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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