

JOB DESCRIPTION

JOB TITLE:	Medical Device Regulatory Project associate Manager/Manager/Senior Manager (MD-RPM)	TRAVEL REQUIRED:	Possible domestic
APPLY	info@bla-regulatory.com	POSITION TYPE:	full time/Contractor remote or office

JOB SUMMARY:

The Medical Device Regulatory Project Manager (MD-RPM) is a regulatory specialist with project management capabilities responsible for leading the end-to-end planning, coordination, and execution of assigned deliverables. The MD-RPM contributes to regulatory submission strategy, identifying submission risks and opportunities while leading simple through more complex regulatory applications and managing procedures through approval.

JOB DESCRIPTION

RESPONSIBILITIES

- Analysis of regulatory procedures and special designations used during development, authorizations, and extension of the medical device product.
- Lead and/or contribute to the planning, preparation (including authoring where relevant) and delivery of simple and with experience, increasingly more complex submissions throughout the product's life cycle.
- Coordinate the input, maintenance, and revision in the project plans for assigned projects and highlight unforeseen changes in resource demand on time to Project Lead.
- Identify regulatory risks and propose mitigations to Project Lead and designated stakeholders.
- Support operational and compliance activities for assigned deliverables
- Develop and contribute to process improvement such as SOPs

EDUCATION AND EXPERIENCE REQUIREMENTS

- Relevant University Degree in Science or Marketing management related discipline
- 2-5 year US and/or EMA or KFDA or PMDA or NMPA Regulatory experience within the medical device filed, or at a health authority
- General knowledge of medical device development
- Strong project management skills
- Leadership skills, including experience leading multi-disciplinary project teams
- Managed regulatory deliverables at the project level
- Thorough knowledge of the medical device development process
- Bi-lingual is preferred but not required: with English as the primary language plus any of Chinese, Korean or Japanese