BLA REGULATORY

JOB DESCRIPTION

JOB TITLE:	Regulatory associate Manager/ Manager/Senior Manager	JOB CATEGORY:	Regulatory Affairs
DEPARTMENT:	Regulatory Project Management	JOB CODE/ REQ#:	RPM/2022-04
LOCATION:	Preferred in Maryland, USA	TRAVEL REQUIRED:	Possible domestic
LEVEL/SALARY RANGE:	Competitive based on experiences and education	POSITION TYPE:	OPT/Part-time /full time/Contractor

JOB SUMMARY:

The Regulatory Project Manager (RPM) is a regulatory specialist with project management capabilities responsible for leading the end-to-end planning, coordination, and execution of assigned deliverables. The RPM contributes to regulatory submission strategy, identifying submission risks and opportunities while leading simple through more complex regulatory applications and managing procedures through approval. The RPM provides regulatory expertise and guidance on procedural and documentation requirements to internal and external stakeholders, working flexibly within and across regions to ensure the delivery of business objectives.

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RESPONSIBILITIES

- Understand the regulatory framework, various types of applications and procedures with US focus.
- Provide regulatory input on procedural and documentation requirements as defined by Health Authorities for assigned deliverable(s)
- US regulatory experiences with entire IND management, preparation, and submission.
- Review of documents (e.g. response documents, study protocols, PSRs, etc.).
- Analysis of regulatory procedures and special designations used during development, authorizations, and extension of the product.
- Develop, execute, and maintain submission delivery plans, submission content plans, and proactively provide status updates to designated stakeholders.
- 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, including generating submission plans, submission tracking, TMF, and document management utilizing the support and input of CROs and/or alliance partners where relevant.
- Develop and contribute to process improvement such as SOPs

EDUCATION AND EXPERIENCE REQUIREMENTS

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- Relevant University Degree in Science or related discipline
- 3-7 years US Regulatory experience within the biopharmaceutical industry, or at a health authority
- General knowledge of drug development
- Strong project management skills, Leadership skills, including experience leading multi-disciplinary teams

PREFERRED SKILLS

- 3-7 years Regulatory experience
- Managed regulatory deliverables at the project level
- thorough knowledge of the drug development process

SKILLS AND CAPABILITIES

- Excellent written and verbal communication skills in English and -Chinese, or -Korean, or -Japanese bilingual preferred, but not required.
- Cultural awareness
- Scientific knowledge sufficient to understand regulatory issues and facilitate scientific discussions
- Proficiency with common IT, project management and document management tools
- Ability to work independently and as part of a team
- Influencing and stakeholder management skills
- Ability to analyze problems and recommend actions
- Continuous Improvement and knowledge sharing focused

Contact	info@bla-regulatory.com	Post date:	30 Apr. 2022