JOB DESCRIPTION

JOB TITLE:	Regulatory Project associate/manager - Bi-lingual: English-Korean	JOB CATEGORY:	Regulatory Affairs
DEPARTMENT:	Regulatory Project Management	JOB CODE/ REQ#:	PRA/M-2-4/21-02
LOCATION:	Prefer in US/Canada, but can be in Asia	TRAVEL REQUIRED:	Possible domestic
LEVEL/SALARY RANGE:	Competitive based on experiences and education	POSITION TYPE:	Bi-lingual: English-Korean, OPT/Part-time /Contractor
CONTACT	info@bla-regulatory.com	DOCUMENT REQUIRED FOR APPLYING	Cover letter and CV

JOB SUMMARY:

The Regulatory Project Associate to Manager (RPA/M-2-4) is a regulatory specialist with medium project management capabilities responsible for project management of IND and NDA/BLA. The RPA/M-2-4 contributes to regulatory execution strategy, identifying project risks and opportunities. The position should provide 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. The RPA/M-2-4 may also support business development as needed by the Company.

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RESPONSIBILITIES

- Understand the regulatory framework, including regional trends, for various types of applications and procedures for small and large molecules across all regions.
- Provide regulatory input on procedural and documentation requirements as defined by Health Authorities for assigned deliverable(s).
- Submission delivery strategy of all dossiers and all application types per market and/or region.
- Genenral 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.

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- Use and share best practices, when handling various applications and procedures during interactions with health authorities and in day-to-day work, while operating in a highly dynamic environment.
- 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 from either a global and/or regional perspective.
- 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

- Relevant Bachelor's Degree or higher in Science or related discipline
- Regulatory experience within the biopharmaceutical industry, or at a health authority, or other relevant experience with at least 1 yr
- General knowledge of drug development
- Strong project management skills of English and Korean
- Leadership skills, including experience leading multi-disciplinary project teams

PREFERRED SKILLS

- Regulatory experience
- Managed regulatory deliverables at the project level
- Thorough knowledge of the drug development process
- English and Korean

SKILLS AND CAPABILITIES

- Excellent written and verbal communication skills in English and Korean bilingual
- 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