JOB DESCRIPTION

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
JOB DESCRIPTION

- 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