Department	Regulatory Affairs
Position	Regulatory Affairs Specialist– Clinical Projects/CMC/NDA
Reports to	GM – RA & QA
Location	Whitefield, Bangalore

The **Regulatory Affairs - Clinical Trial Manager** enables the development of organizational and people capabilities of the future, we support and optimize the delivery of projects and initiatives to the organization both on the molecule and molecule-enabling portfolio.

We are responsible for enabling the future of clinical trials from a regulatory perspective by pushing boundaries to deliver medical solutions now in order to transform patients' lives.

KEY RESPONSIBILITIES SHALL INCLUDE:

- Responsible to lead and implement all global CMC submission activities for assigned projects/products, while applying the global strategy into submissions
- Ensuring the required documentation and any content, quality and/or timelines for global submissions are communicated to the appropriate teams and tracked accordingly.
- Working closely with the Clinical Trials Coordinator and other clinical project related teams, will have strategic responsibility for clinical trial related regulatory tasks.
- Management of Core documents and amendments for USA, EU, China, Australia & other regulated markets, as applicable. This includes planning, filing, compilation, dispatch, coordination with internal departments and the affiliates, tracking of submissions and approvals in appropriate systems. Including product applications.
- Review the ANDA/IMPD/IND/NDA/CMC documentation for submission in applying global regulatory strategies, assuring regulatory compliance and Product Life Cycle Management
- Authoring and Review of IND/IMPD/NDA and ANDA submissions to US FDA, EMEA, China FDA & other regulated markets, as applicable.
- Authoring and Review of pre-submission Meeting requests and briefing packages for IND/CMC/NDAs and ANDAs
- Complex and complex submissions, independently fulfill the following responsibilities:
- Conduct research of existing product data relative to global or regional regulatory requirements for the preparation of gap analyses, product development plans, and other regulatory submissions.
- Contribute to or prepare administrative and technical components of regulatory agency submissions for the IND, for pre-approval submission packages, for product registration applications, and for post-approval maintenance. Prepare briefing packages for regulatory agency meetings or scientific advice and contribute to or

support the agency interactions. Similarly for other submissions like ANDA, CMC, etc

- Manage and/or operationalize the delivery of day-today regulatory activities for assigned project according to agreed timelines, scope of contract, budgets, and strategies.
- Participate as regulatory support on multidisciplinary project teams, which may include clinical and other technical experts, to develop products throughout their life cycle.
- Act as a subject matter expert and help the team members with day-to-day trouble shooting activities, presenting solutions to project related problems.
- Prepare estimates for conducting regulatory services as part of single or multiple service proposals.
- Support meetings with clients to discuss proposals, the status of ongoing projects, and as part of general business development activities.
- Ensure compliance with appropriate global regulatory requirements and the company's policies and processes.
- Prepare training materials and share best practices in the regulatory area, both internally and externally.
- Participate as regulatory support in internal or external project audits.
- Participate as regulatory support on internal cross-functional initiatives.
- Contribute to the creation and/or maintenance of SOPs and other process related documentation as required.
- Provide support in oversight to team members in the execution of their project responsibilities.
- Capable of identifying when to ensure line support required to provide additional guidance and direction.
- Regulatory strategic support for IND/IMPD/NDA and ANDAs during development stage of various dosage forms specifically in Ophthalmic.
- Handling of Health Authority queries with strategies and response package preparation
- Evaluation of change controls and providing regulatory strategies for post approval changes submissions.
- Responsible for assisting developmental strategy of various dosage types including complex dosage forms
- Responsible for Authoring and final review of Meeting Requests and Packages for Pre-IND, Pre-ANDA meeting requests for Complex Products per GDUFA & PDUFA. Must have current knowledge of GDUFA & PDUFA guidelines, as well as other similar global guidelines.

- Manage Pharmacovigilance documentation, including Drug Safety Update Reports, Periodic Safety Update Reports, Investigation Brochures, Clinical Trial Reporting, and clinical trial applications

QUALIFICATION REQUIREMENTS

- Pharmacy degree, preferably in a science-related field or equivalent experience in science/regulatory field.
- Demonstrated experience in contributing to the preparation of regulatory submissions including, for example IND, PMA, NDA, MAA, and CTD, including electronic submissions.
- Good negotiating and communication skills with ability to challenge, if applicable.
- Effective communication, organizational, and interpersonal skills.
- Ability to work independently and to effectively prioritize tasks.
- Ability to manage multiple projects.
- Knowledge and ability to apply GCP/ICH/GDUFA/PDUFA and applicable regulatory guidelines.
- Additional advantage, if has NMPA guidelines knowledge and application experience
- Excellent interpersonal / communication skills including excellent written and verbal communication skills.
- Excellent customer service skills, with the ability to work both as a team member and independently.
- Good quality management skills.
- Advanced skills in Microsoft Office Applications.
- Ability to interact with staff from multiple departments and offices to establish project standards.
- Good initiative, adaptability, and pro-activity.
- Strong analytical skills, good attention to detail.
- Ability to work concurrently on projects, each with specific instructions that may differ from project to project.
- Fluent in speaking, writing, and reading English.