Department	Regulatory Affairs
Position	Senior Manager – Regulatory Affairs
Reports to	GM – RA & QA
Location	Whitefield, Bangalore
Experience	Minimum 12 years
Qualification	B.Pharm / M.Pharm / M.Sc.

KEY RESPONSIBILITIES SHALL INCLUDE:

- Preparing & Filing of product applications (Solid Dosage Forms & External preparations) in USA, EU, China, Australia etc and other regulated market as applicable.
- Planning & Execution of Product Dossiers as per scheduled planner & submissions
- Review of dossiers to ensure major queries are not expected from any Regulatory Agencies
- To prepare and provide strong Regulatory Strategy specific to the therapeutic category of the product for the successful Pre-IND meeting.
- Review of Pre-Clinical Studies design as per the Global submission requirements
- Review and response of Product related Citizen Petitions
- Strong knowledge on GDUFA /PDUFA related activities
- Review of Pre-Clinical study Reports and compilation of STF's
- Selection of suitable Reference Product and design the BE / BA study as per the country requirements
- Preparation and compilation IND draft labeling as per the New Drug Application requirements
- Strong knowledge on handling of New Drug Applications
- Provide technical assistance to the team details of Pre-Clinical studies design and provide scientific evidence
- Review of different phases of Clinical Trial Applications
- Handling of Amendments to FDA (Gratuitous, complete response, Telephonic labeling, Easily correctable Deficiencies and Bio-Amendments)
- Drafting of Patent Applications for both API & Formulations
- Handling of Supplements (PAS,CBE-0 and CBE-30) and Annual reports to USFDA
- To prepare and provide strong regulatory strategy specific to the therapeutic category of the product for the successful Pre-IND meeting outcome with the help of consultant
- To provide logistic for the arrangement of Pre-IND meeting with USFDA
- Co-ordination of cross functional teams (CFT's) / contract research organizations (CRO's) to get technical documents required for the preparation of Pre-IND meeting briefing package
- Review of CMC, Non-Clinical and Clinical documents for scientific and technical content and compliance with regulatory requirements
- Review of investigator brochure in accordance to the country regulatory requirements
- GAP analysis report preparation with remediation
- Compilation and preparation of DMF Dossiers in eCTD format (open part & restricted parts)
- Handling of Lorenz software and publishing the eCTD independently.
- Knowledge of serialization and handling of the concern activities pertaining to RA like creation of product profile data and submission of batch data to EU HUB.

- Pre-IND meeting briefing package compilation, preparation and finalization and submission with USFDA/EMA/AUS with the help of consultants
- To participate in all the R&D meetings and provide regulatory inputs
- To provide regulatory and CMC support for all phases of product development for different types of pharmaceutical products
- Identification of suitable CRO's for conduction clinical trials, patient BE/PK studies & Audits of CRO facilities and negotiation of trial timelines and allocation of studies
- Identification, review and preparation of SOP's related to Regulatory and Clinical Research with the help of Medical affairs as applicable.
- Review of trial related documents: site initiation, monitoring, closure reports/reviewing and overseeing of CRO-SIV's, SMV reports (onsite & offsite)
- Review of different phase study protocols, ICF's, CRF's, TMF's, SMF's , subject diaries, Regulatory documents and clinical trial reports as per the ICH-GCP, protocol and applicable guidelines
- To ensure Regulatory Compliance in the organization
- To advise and guide research and development on Regulatory requirements for new product development and registration of the products with USFDA / EU / EMA
- Primary point of contact between cross functional teams and consultants
- Review, finalization and approval of license related documents to start API and formulation R&D activities and also ensuring timely submission and early approval from local regulatory authorities
- To bring the best talent pool to the organization by identifying, evaluating and engaging for resources hiring and talent management etc.
- Correspondence with applicable regulatory/PhV consultant.

Desired Candidate Profile:

- A Pharmacy/ Science Graduate/Postgraduate from well-established Regulatory background with 10 to 12 years sound experience in reputed Pharma Organizations
- Ability to work both independently and within a team structure
- Proven ability to lead, influence and motivate colleagues and external partners.
- Good knowledge of guidelines from EUDRA, FDA, TGA, MCC and ANVISA
- Strong planning, presentation, and interpersonal skills
- Strong work ethic, self-motivation, dedication, results orientation
- Significant working knowledge of the pharmaceutical product development process (eg. Regulatory requirements, GMP, Clinical strategies, drug delivery etc.)
- Understanding of the role of drug delivery in the pharmaceutical marketplace in both scientific and business context (eg. Market exclusivity requirements, role of IP in life cycle management) is a plus
- Working knowledge on the various Biotechnological techniques, Gene therapy and Gene silencing techniques is a plus.
- Excellent in written and spoken English
- Multitasker, strong in systems, process
- Can do attitude is a must.
- Evaluation of strategic option, costs, time and completion strategy
- Strong internal co-ordination skills