SOVEREIGN

SOVEREIGN PHARMA PVT. LTD.

SUMMARY:-

Role	: Executive – Regulatory Affairs
Experience	: 4 to 5 years.
Education	: B.Sc./M.Sc./ B.Pharm/ M.Pharm / PhD
Industry type	: Pharmaceutical / Health care
Functional Area	: Regulatory Compliances.
Salary	: Negotiable
Age	: 25 to 35 years.

DESIRED CANDIDATE PROFILE:-

- Minimum B.Sc / B.Pharm, etc.
- Minimum 3 + years pharmaceutical regulatory experience, ideally in injectables.
- Experience and knowledge in the preparation and managing of major regulatory submissions.
- Good knowledge of c-GMP principles.
- Demonstrate effective cross-cultural awareness and capabilities and sensitivity for a multicultural/multinational environment.
- Good knowledge of written and spoken English, and a sound understanding of working with standard software (MS Office, Lotus).

JOB DESCRIPTION:-

- To comply with all the regulatory requirements.
- Responsible for development and implementation of global regulatory strategies.
- Hands on knowledge of dossier preparation & ANDA.
- Represent the company at regulatory authority meetings.
- Provide regulatory support for various departments, projects, and teams.
- Identify and assess regulatory risks associated with product development.
- Interact with a wide variety of outside contacts, including contractors, consultants, corporate partners and regulatory agency personnel and multiple departments at all levels.
- To handle FDA related activities in totality.
- Responsible for all aspects of regulatory documents, submissions and Audit compliance issues. Communicate with FDA representatives (e.g. respond to FDA inquiries; provide the FDA with up-to-date information regarding its filings…)
- To support Regulatory audits activities, preparation and actual audit and compliance.