



JOB DESCRIPTION

ROLE: Regulatory Affairs Manager (Toxicology/ Pharmacology)

SALARY AND BENEFITS: Negotiable

REPORTS TO: Head-Scientific and Regulatory Affairs

LOCATION: Baroda, India

PRIMARY RESPONSIBILITIES:

- Responsible for providing toxicological expert evaluation for all drug products and drug substances.
- Responsible for providing pharmacology and regulatory support to obtain Marketing Authorisations.
- Clinical and non-clinical expert evaluation for all products.
- Assessment of scientific data/literatures and review of scientific justifications.
- Provide input into all stages of the company's development and portfolio of products and to develop strategies to ensure a complete and rapid development.
- Co-ordination with CROs for toxicological and BE studies.

SECONDARY RESPONSIBILITIES:

- Management of regulatory submissions and procedures (e.g. for national or centralised scientific advice procedures, clinical trial applications, marketing authorisation applications, post-authorisation procedures, waivers and/or deferrals).
- Review and approval of overviews and summaries. Manage the preparation of Regulatory documentation, focusing on clinical and non clinical.
- Identify Regulatory opportunities or issues and problems related to designated products/projects.
- Licensing and 'due diligence'.
- Evaluation of Regulatory strategy documents, PDE documents and development documents.
- Ensuring that all processes and data are kept in an inspection and audit ready condition at all times.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- More than 10 years of core Pharmacology (Clinical & non-clinical)/Toxicology/Regulatory Affairs experience.
- Qualification: MBBS/MD/Mpharm/MVSc/PhD (Pharmacology/Toxicology).
- Clinical & non-clinical studies and regulatory submission experience.
- Strong EU or International submission experience
- Candidates with Toxicology experience is preferred.
- Line management and team leadership experience.
- Excellent managerial skills.
- Experience with Specialty care and Paediatrics is advantageous.