

JOB DESCRIPTION

ROLE: Pharmacology Manager

SALARY AND BENEFITS: Negotiable

REPORTS TO: Pharmaceutical Development Director

LOCATION: Vadodara

PRIMARY RESPONSIBILITIES

- He will be responsible for providing and managing regulatory support to the company in order to obtain Marketing Authorisations. He will need to 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.

SECONDARY RESPONSIBILITIES

- Preparation and 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).
- Writing 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'.
- Assessment of scientific data.
- Regulatory intelligence
- Regulatory strategy and contributing to development programmes.
- Ensuring effective and on time processing of all pharmacovigilance data received in the department to meet internal and external timelines. This will include management of PSuRs, Safety data exchange agreements, third parties performing PV work, patient support programmes, social media, market research, Risk Management, and creating and updating local Standard Operating Procedures
- 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 core Regulatory Affairs experience
- Broad range of regulatory submission experience, including eCTD publishing
- Strong EU or International submission experience
- Clinical or CMC background experience
- Line management and team leadership experience
- Life Science Degree
- Excellent managerial skills
- Experience with Specialty care and Paediatrics is advantageous