B & S GROUP "Believe in us"

JOB DESCRIPTION

ROLE: Regulatory Manager
SALARY AND BENEFITS: Negotiable
REPORTS TO: Pharmaceutical Development Director
LOCATION: Vadodara

PRIMARY RESPONSIBILITIES

- You will be involved in the submission and monitoring of successful pharmaceutical licence applications by liaising with various governing boards to obtain granted licences as soon as possible.

SECONDARY RESPONSIBILITIES

- Developing and executing regulatory strategy for new products.
- Preparing dossiers accurately for submission to governing boards as well as retaining and organising relevant licence documentation efficiently.
- Reviewing regulatory documents such as manufacturing batch records, packaging batch records, analytical method, validation protocol and reports.
- Responsible for compiling regulatory documents including all Modules for submission according to local requirements.
- Responsible for coordinating with cross-departmental teams such as Contract Lab and Contract Manufacturer for timely submission if required, collection of documents, review of documents and resolving any regulatory discrepancies.
- Keeping up to date with regulatory issues in drug development processes and working to eliminate or minimise regulatory barriers.
- Responsible for deficiency reply received from agency.
- Maintenance of database with regulatory submission and approval.
- Managerial duties:
    - Organising daily objectives/tasks in line with KPI's.
    - Conducting one to ones and team meetings regularly.
    - Developing the teams' skills to ensure work is carried out as efficiently and accurately as possible.
    - Identify skill shortfalls in team members and put in place development plans to address these.
- Provide holiday and absence cover when required, in other roles.
- Ad hoc projects when required.
- Any other duties as required.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Previous experience in a similar role is required.
- Knowledge of completing a dossier for EU countries through DCP, MRP, National procedures.
- Knowledge of completing a dossier in Nees or eCTD submission.
- Clear communication skills both written and verbal.
- Can demonstrate excellent analytical skills.
- Ability to demonstrate openness to change.
- High attention to detail.
- A conscientious and innovative individual who shows attention to detail.
- Possess good working knowledge of Microsoft Office.
- Ability to keep up-to-date with Pharmaceutical trends and developments within the industry.