



JOB DESCRIPTION

ROLE: Regulatory Affairs Officer
SALARY AND BENEFITS: Negotiable
REPORTS TO: Regulatory Manager
LOCATION: Ruislip

The B & S Group is now looking to recruit a Regulatory Affairs Officer to join our Regulatory Team. Reporting directly in to the Regulatory Manager you will be working within a fun, innovative and fast paced environment.

PRIMARY RESPONSIBILITIES

You will be involved in the writing and review of module 1 – 5 for application submissions to various governing boards to gain granted licenses as soon as possible. Further to this maintaining product life cycle of the product after the grant of licence.

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
- Proactively keeping up to date with Regulatory guidance
- Any other duties as and when 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
- Good knowledge of life cycle management of products
- 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.