# JOB DESCRIPTION

**ROLE:** Senior Regulatory Affairs Executive
**SALARY AND BENEFITS:** Negotiable
**REPORTS TO**: Regulatory Manager
**LOCATION:** Ruislip

The B & S Group is now looking to recruit a Senior Regulatory Affairs Executive 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 have the responsibility of supervising a junior team based in the UK. 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.