# JOB DESCRIPTION

**ROLE:** Regulatory Clinical Graduate
**REPORTS TO**: Regulatory Manager
**LOCATION:** Ruislip

B & S Group are now looking to recruit for an ambitious Graduate who is interested in kick starting their career in a fast-moving company. You will undergo a training programme aimed at giving you understanding of our business whilst gaining industry experience. It is also structured to give you the support, guidance and solid professional platform necessary to be able to find the right path, along which to take your first steps into a future career with B&S Group.

## PRIMARY RESPONSIBILITIES

Responsible for coordinating with various departments for documentation required for submission, ensuring the documentation is of high quality and can be submitted to Health Authority
Review scientific literature to ensure the documentation written is of high standards for submission.

## SECONDARY RESPONSIBILITIES
**Regulatory Affairs**

- Review of Product Information for submission purpose to the health authority
- Responsible for reviewing literature and ensuring the prepared documentation are of high quality.
- Supporting the team with review and coordination of submissions to the Health Authority
- To support the review of clinical and non-clinical sections of the dossier
- Responsible for planning the workload for defined product responsibilities in consultation with the Regulatory Manager.
- Keep up-to-date with Regulatory guidelines and reviewing the impact this will have on products
- Responsible for responding to regulatory queries and proactively troubleshooting technical/quality issues relating to preparations and submissions
- Supporting the Regulatory Manager in daily activities which are required for business
- To ensure submissions of licence variations and renewals to strict deadlines
- Follow up with regulatory authorities on submissions and regulatory issues
- Other duties to meet business needs
- Any other ad hoc duties as and when required

## ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- MSc/BSc Pharmacology or equivalent
- MSc Pharmaceutical Science
- Good knowledge of ICH Guidelines and EMA guidelines
- Ability to prepare high quality regulatory applications and the ability to communicate effectively
- Ability to handle multiple tasks in a fast-paced and constantly changing environment
- Clear verbal and written communication skills is essential
- High attention to detail
- Ability to work on own initiative and in a team
- Experience of working on the Microsoft Packages including Outlook Internet Explorer
- Ability to manage time well

- Ability to adapt to change