

**JOB DESCRIPTION**

**ROLE:** Quality Compliance Manager / Responsible Person

**REPORTS TO**: Clinical Director

**LOCATION:** PERIVALE

The B & S Group is a privately owned pharmaceutical company which manufactures and distributes pharmaceutical and healthcare products to the UK market. Established in 1999 we offer a wide range of products and services which includes specials, generic drugs, branded medicines, parallel trade and over-the-counter (OTC) medicines. Having undergone two acquisitions since 2010, we are continuing to strengthen and growing rapidly.

**Responsibilities**

* Responsible for ensuring the licence provisions are observed and met
* To carry out the duties of the Responsible Person named on the Wholesale Dealer's Authorisation
* Responsible for ensuring that operations do not compromise patient safety and the quality of supplied medicines
* Responsible for ensuring that a compliant quality system is established and maintained
* Responsible for ensuring GMP and GDP compliance and best practice within all regulated activities
* Responsible for ensuring audits of the quality system are performed and to carry out independent audits
* Responsible for ensuring that adequate records are maintained
* Responsible for ensuring that adequate resource and capabilities exist within the quality assurance team and that all personnel are trained and developed in line with the requirements of their role.
* Responsible for the leadership of the quality assurance team and line management of staff, ensuring a high level of team motivation and morale
* Responsible for ensuring full and prompt cooperation with product licence holders is given in the event of recalls.
* To identify risks and to take necessary preventative measures pro-actively
Hosting and reporting of Regulatory inspections, Client Audits and supplier audits
Liaise with regulatory authorities (MHRA, Home Office) on Licence applications, drug returns and product recalls.

**EXPERIENCE**

 You will have previous experience of the storage and distribution of pharmaceutical products and current GDP standards and procedures. (Desirable)

* Pro-active and solutions driven, with the ability to work to strict deadlines with a high level of accuracy
* Degree in Quality Management life science or related field (desirable)
* Excellent communication skills: verbal and written
* Proven leadership capabilities in a senior quality role
* Ability to communicate effectively at all levels of the business
* Extensive knowledge of GMP and GDP and MHRA Guidance Note 14
* Practical experience in Supply Chain, Production and Quality Assurance
* Experience of hosting MHRA inspections, client audits and self-inspections
* Fully IT literate: Microsoft Outlook, Word, Excel, SAGE (desirable)
* Highly self-motivated with strong inter-personal skills
* Effective planning, organisational and administrative skills
* Ability to work with cross-functional teams on new process projects, incident investigation, identification of root causes and process improvements