

## BPL-JOB DESCRIPTION

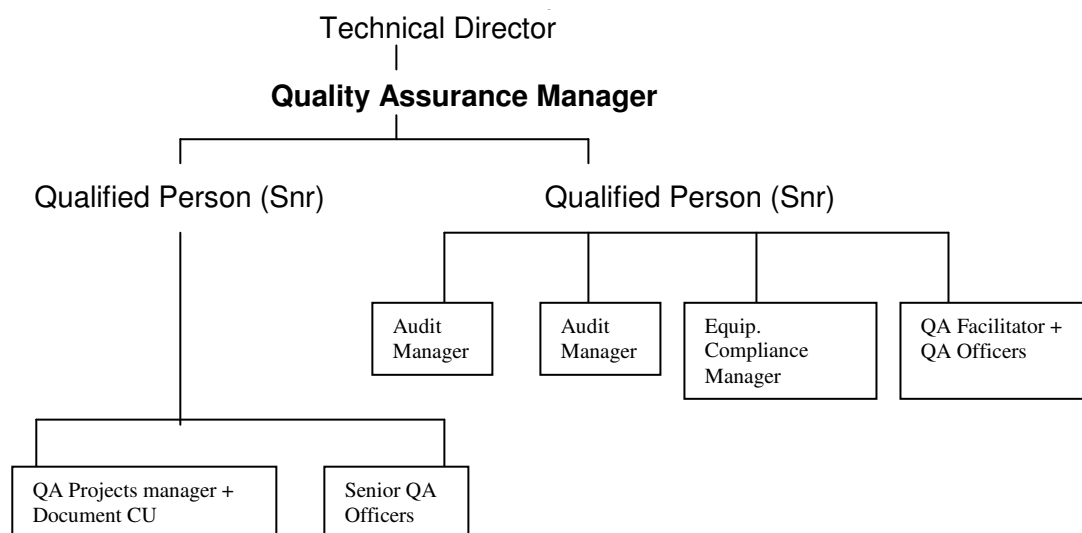
### Post Details

|                                |  |
|--------------------------------|--|
| <b>Job Title:</b>              | Quality Assurance Manager (Qualified Person) |
| <b>Generic Job Title:</b>      |  |
| <b>Band:</b>                   | 8D   |
| <b>Department/Directorate:</b> | Technical                                    |
| <b>Accountable to:</b>         | Technical Director                           |

### Main Job Purpose

To manage those sections of the Quality Department with responsibility for ensuring GMP and regulatory compliance. Directly, and through the staff of the QA Support, to undertake the functions of Qualified Person, in particular the release of product judged suitable for its purpose.

### Organisation Structure



## Key Duties and Responsibilities

- The Quality Assurance Manager (QAM) is responsible to the Technical Director (BPL) for ensuring the manufacturing activities proceed in accordance with current principles of Good pharmaceutical manufacturing Practice, and specifically in accordance with BPL policies, procedures and standards, in particular those procedures set out in licences granted to BPL.
- The QAM will be cited on BPL's Manufacturer's Licences as a "Qualified Person" and, having satisfied him / herself that GMP and regulatory requirements have been met, the Quality Assurance Manager will release product for sale. Also cited the Responsible Person on the Wholesalers Dealer's Licence responsible for compliance to legislation and GDP related to wholesaling medicinal products.
- The QAM will be primarily responsible for the recall and customer complaints systems.
- The QAM will be primarily responsible for chairing the QMR and CAPA meetings
- The QAM will be responsible for overseeing GMP training on site.
- The QAM will contribute directly, and through the staff of sections reporting to him / her to the establishment and maintenance of such quality systems as are necessary for the effective operation of BPL.
- Through the QA Support and the Document Control Unit, the QAM will establish and maintain such documentation systems as are necessary to demonstrate compliance with GMP and regulatory requirements, and will review the records of manufacture, prior to release for sale; this function includes a system for monitoring, and remedial action in respect of product complaints;
- The QAM will establish and maintain systems for audit of those operations involved in the development, manufacture and distribution of BPL's products, this will include GMP, GCP and GLP;
- The QAM will work closely with the training co-ordinators, and with line managers in

other departments, to provide training programmes relating to GMP and QA.

- The QAM will work closely with regulatory staff in the generation and maintenance of site / product registration files.
- The QAM will provide the prime point of contact between BPL and control agency inspectors, on the occasion of site inspection.

**Acceptance and Review**

Accepted

Manager..... Date .....

Jobholder..... Date .....

Reviewed

Manager..... Date .....

Jobholder..... Date .....