JOB DESCRIPTION

ROLE: Qualified Person
REPORTS TO: Managing Director
LOCATION: Ruislip

PRIMARY RESPONSIBILITIES
This person would be primarily responsible for the certification of products. Other responsibilities include conducting audits while being able to display and communicate an in-depth knowledge of cGMP regulatory standards, licensing the unlicensed products and sterile production.

SECONDARY RESPONSIBILITIES

- Responsible for the review and approval of Standard Operating Procedures, review and approval of study protocols, and auditing (internal and external).
- Auditing for GMP, GCP GDP and GLP purposes, experience of Quality Management Systems covering all aspects of Licensed Manufacturing sites
- Active participation in troubleshooting of GMP, GCP and GLP issues.
- Provide input into the Regulatory strategy for the development of pharmaceutical products in the UK
- Licensing the unlicensed medicines for the UK market
- Liaising with the Regulatory Authority/MHRA contact for all pharma products sold in UK
- Working cross functionally with Pharmacovigilance, Regulatory Affairs, Clinical Research
- Being involved in all aspects of the sterile production including design, installation and operational
- Plan, execute and supervise the standard training programme for all new employees and maintain continuous training for all staff
- Develop training courses as a separate business unit within the department
- Maintain all professional knowledge databases
- Ad hoc projects
- Any other duties as and when required

ESSENTIAL EXPERIENCE

- Eligible to be named as a Qualified Person
- Preferable Experience in the licensed manufacture of the following:
  - Oral solid dosage
  - Oral liquid dosage
  - Sterile dosage form
  - Semi-solid / topical products (Creams, liquids and ointments)
- Practical experience of auditing for GMP, GCP GDP and GLP purposes
- Experience of Quality Management Systems