Job description

Job title	QC Technician
Directorate	Quality
Pay band	Level 5
Responsible to	Analytical QC Lab Manager
Base/location	Porton
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma, Porton Down has approximately 350 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The department carries out the manufacture of Erwinase and Anthrax as well as contract manufacturing projects.

Analytical Quality Control Laboratory

The Analytical Quality Control Laboratory is part of the Development and Manufacturing Group at Porton Down which develops and manufactures biopharmaceutical products according to cGMP requirements. The laboratory is responsible for provision of analytical chemistry services to support quality control testing of products, raw materials and water systems. A stability study programme is also maintained to meet regulatory requirements for marketed products.

JOB SUMMARY

To provide support for the chemical and biochemical analyses performed by QC Technologists within the Analytical QC department to support the manufacture of Porton Biopharma's licensed pharmaceutical products; as required by EU Directive 91/356/EEC for GMP compliance.

Communication and key working relationships

Internal

- QC Technologists
- QC Laboratory supervisors
- QC Laboratory Manager
- Stability Manager
- Analytical QC Manager
- Quality Assurance personal
- Pharm stores
- Validation
- Safety department

External

- Contract Laboratories.
- Participation in audits by external customers and regulatory bodies e.g. MHRA and FDA.
- Suppliers of instrumentation and chemicals.
- Engineers

MAIN DUTIES AND RESPONSIBILITIES

- Carry out stock checks for Laboratory and reagents
- Place orders for routine orders and one off items
- Maintain stock lists
- Receive and book in delivered consumables and reagents
- Removal of out of date materials and waste from the QC laboratories
- Assist with housekeeping in Analytical QC
- Disposal of toxic, hazardous and non-hazardous waste generated within Analytical QC
- Calibration and scheduled maintenance of analytical equipment
- Routine QC testing
- To ensure GMP documentation practises are followed when completing the necessary documentation.
- Undertake work in accordance with Porton Biopharma's Code of Safety Practice and Quality Systems.
- Maintain training records.

Other

The above is only an outline of the tasks, responsibilities and outcomes required of the role. You will carry out any other duties as may reasonably be required by the directorate.

The job description and person specification may be reviewed on an ongoing basis in accordance with the changing needs of the organisation.

Professional development

You should pursue a programme of continuous professional development in accordance with any relevant professional registration or statutory requirements, while maintaining appropriate awareness of service provider requirements.

Person specification

Description	Essential	Desirable	Assessment
Qualification			
2 A-levels in numerate / science subjects	√		AI
Degree in Chemistry or Biochemistry		√	AI
Knowledge and experience Experience as defined by type/level (not length)			
Working Knowledge / Experience of a regulated or cGMP environment		√	AI
Experience of following written instructions	√		AI
Experience of following SOPs or GMP documentation		√	AI
Experience using standard analytical laboratory equipment such as pH meters, balances, pipettes		√	AI
Skills and capabilities			
A good level of computer literacy, able to utilise Microsoft office software	√		AI
Able to prioritise and manage time to meet deadlines	√		AI
Ability to organise personal workload	√		AI
Able to display flexibility to deal with changing priorities	√		AI

Equality and diversity			
An understanding of and commitment to equality of opportunity and good working relationships, both in terms of day-to-day working practices, but also in relation to management systems	✓		I
***Assessment will take place with reference to the following information** **A = Application form I = Interview C = Certificate T = Test**			

Job description agreed with the post holder:

Employee signature: …….. Date:……

Print name:…….....

Manager's signature:…….. Date:……

Print name:…….....…