Job description

Job title	QC Technician
Division	Quality
Career Level	5
Responsible to	QC First Line Manager

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized company performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The Company carries out the manufacture of Erwinase® and Anthrax Vaccine as well as contract manufacturing projects.

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 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 Analysts
- QC Technicians
- QC Senior Analyst
- QC First Line Manager
- Analytical QC Manager
- Quality Assurance personal
- Pharm Stores
- Validation
- Calibration
- Health & Safety
- Engineering
- Development

External

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

MAIN DUTIES AND RESPONSIBILITIES

- Perform stock checks and maintain stock levels for laboratory consumables, reagents and office supplies.
- Place orders for all consumables and chemicals for the laboratories/offices and one-off items
- Data entry into Excel spreadsheets and other databases
- Archive old documents
- Delivery both samples and Reference Standard between the Stability department and the QC laboratories
- Receive and book in delivered all consumables and reagents for the laboratories
- Removal of out of date materials and waste from the QC laboratories
- Assist with housekeeping in QC Analytical in both laboratories and office space.
- Disposal of toxic, hazardous and non-hazardous waste generated within Analytical QC
- Perform basic QC tests, such as Conductivity and Description testing
- To ensure GMP documentation practices are followed when completing the necessary documentation, such as QC forms
- Undertake work in accordance with Porton Biopharma's Code of Safety Practice and Quality Systems
- Maintain training records, keep accurate records and filing systems
- To ensure documentation (SOP's, Specifications, Monographs, MSDS's etc) within the department are current and copies are available
- Organise calibration and scheduled maintenance of basic analytical laboratory equipment, such as Pipettes.
- Assist with sample receipt and booking samples in to the QC department

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 organization.

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.

You should adhere to PBL values and behaviours:

- Passion
- Respect
- Integrity
- Diligence
- Excellence in Execution.

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	☒	
A good standard of written and spoken English Language	☒	
Qualification		
2 A-levels in numerate / science subjects	☒	☐
Degree in Chemistry or Biochemistry	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Working Knowledge/Experience of a regulated or cGMP environment	☐	☒
Experience of following written instructions	☒	☐
Experience of following SOPs or GMP documentation	☐	☒
Experience using standard analytical laboratory equipment such as pH meters, balances, pipettes	☐	☒
Experience of Microsoft office (Excel and Word)	☒	☐
Skills and capabilities		
A good level of computer literacy, able to utilise Microsoft office software	☒	☐
Able to prioritise and manage time to meet deadlines	☒	☐
Ability to organise personal workload	☒	☐
Able to display flexibility to deal with changing priorities	☒	☐
High level of attention to detail for data entry	☒	☐
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	☒	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	
Manager Name:	Date:
Manager Signature:	