Job description

Job title	QC Analyst
Division	Quality
Career Level	4
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 undertake the chemical and biochemical analyses to support the manufacture of PBL's licensed pharmaceutical products; as required by EU Directive 91/356/EEC for GMP compliance. To write quality documentation relating to raw materials, water and product testing where appropriate. To ensure that work performed within the laboratories is carried out in compliance with corporate statutory health and safety requirements

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

- To ensure analysis and recording of QC and stability testing is performed in compliance with the statutory requirements of cGMP.
- Responsibility for testing raw materials, in process and finished product samples to ensure that they meet the specifications established in the product licence and internal Porton Biopharma specification documents.
- Responsible for writing Standard Operating Procedures and their associated risk assessments to ensure that those tasks are performed safely.
- Write quality documents e.g. change controls, validation reports, non-conformances and CAPA's where appropriate.
- Organise and liaise with external testing laboratories to arrange correct and on time testing to meet production deadlines or suppliers of equipment or chemicals.
- Organise and liaise with internal departments such as validation, pharms stores and QA where required.
- Maintain an up-to-date awareness of regulatory and scientific developments via courses, meetings and literature.
- Undertake work in accordance with Porton Biopharma's Code of Safety Practice and Quality Systems.
- Maintain training records.
- Cleaning of laboratories.
- Maintenance and calibration of equipment.

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.

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		
Degree or equivalent qualification in Chemistry/Biochemistry or other related subject or previous relevant experience.	☒	☐
Higher degree or equivalent qualification in Chemistry or Biochemistry	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Working Knowledge / Experience of cGMP	☐	☒
Working Knowledge / Experience of the EP and USP	☐	☒
Working Knowledge / Experience of ICH requirements	☐	☒
Previous experience of working in a similar position as a bench analyst following written instructions and comparing analytical results with set specifications	☒	☐
Knowledge / Experience of UV/Vis and FT/IR	☐	☒
Knowledge / Experience of analysing purified water and water for injection by TOC	☐	☒
Basic experience of the out of specification process and carrying out laboratory investigations	☐	☒
Experience using standard analytical laboratory equipment such as pH meters, balances, pipettes	☒	☐
Knowledge / Experience analysing pharmaceutical raw materials	☐	☒
Knowledge / Experience of Waters HPLC systems and associated software or equivalent	☐	☒
Skills and capabilities		
Good communication skills able to communicate technical issues to Supervisors and understand technical instructions	☐	☒
Problem solving skills and ability to respond to sudden unexpected demands	☐	☒
Ability to work on own initiative, organise own workload and prioritise daily work with minimal supervision working to tight and often changing timescales	☐	☒
Ability to use technical software packages	☐	☒

Ability to work as part of a team	☐	☒
Good basic computer skills and literacy	☒	☐
A desire and ability to self-improve and to improve the department	☐	☒
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:	