Job description

Job title	Senior 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.

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 undertake chemical and biochemical analyses to support the manufacture of Porton Biopharma's licensed pharmaceutical products; as required by EU Directive 91/356/EEC for GMP compliance. To supervise and schedule work for QC Analysts. To write quality documentation relating to raw materials, water and product testing. 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
- Laboratory Supervisors
- QC First Line Manager
- Analytical Quality Control Manager

- Quality Assurance personnel
- Production personnel
- Validation personnel
- Pharm Stores personnel
- Engineering personnel
- Development personnel

External

- Contract Laboratories
- Participation in audits by external customers and regulatory bodies eg MHRA
- Suppliers of instrumentation and chemicals

MAIN DUTIES AND RESPONSIBILITIES

- To deputise for the QC First Line Manager when required.
- To supervise junior QC Analytical staff.
- To schedule work for QC Analytical staff members to ensure that manufacturing deadlines are met.
- To ensure analysis and recording of QC and stability testing has been 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.
- Organise and liaise with external testing laboratories to arrange correct and on time testing to meet production deadlines.
- Maintain an up-to-date awareness of regulatory and scientific developments via courses, meetings and literature.
- Responsible for the verification of analytical raw data and release of results from the QC Analytical department.
- Responsible for writing quality records such as non-conformances, CAPAs and change controls.
- Responsible for managing equipment within the QC department and introducing new equipment in to the QC department including completion of the associated quality records such as User Requirement Specifications, System Impact Assessments, IQ, OQ, PQ, Validation Summary Reports, Calibration and Maintenance Schedules.
- Ensuring all equipment within the QC department is calibrated and serviced.
- Purchasing equipment for the QC department.
- Monitor compliance within QC Analytical, identify weaknesses and develop strategies to continually improve systems.
- Managing all activities involved in transferring analytical methods from Development to QC Analytical Services including running analytical methods, writing transfer/validation protocols, executing protocols in the laboratory, writing up the associated transfer/validation reports.
- Undertake work in accordance with Porton Biopharma's Code of Safety Practice and Quality Systems

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 PBL values and behaviors:

- Passion
- Respect
- Integrity
- Diligence
- Excellence in Execution (E^2)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	☒	
A good standard of written and spoken English Language	☒	
Qualification		
Degree in Chemistry/Biochemistry or other suitable degree. Suitable experience may be considered as suitable	☒	
Further degree in Chemistry, Biochemistry or equivalent discipline / membership of a scientific society.		☒
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.	☒	
Previously worked in a similar laboratory as a bench analyst following written instructions and comparing analytical results with set specifications.	☒	
Knowledge / Experience of Enzyme analysis.		☒
Knowledge / Experience of Waters HPLC systems and associated software or equivalent		☒
Knowledge / Experience of Gel Electrophoresis		☒
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 using UV-Vis and FT-IR.		☒
Knowledge / Experience using KF Moisture determination.		☒
Knowledge / Experience analysing purified water and water for injection.		☒
Knowledge / Experience analysing pharmaceutical raw materials		☒
Ability to supervise junior staff and schedule workloads.	☒	
Experienced in supervising junior staff and scheduling workloads in a similar situation		☒
Skills and capabilities		
Good communication skills able to communicate technical issues clearly, both written and verbally with QC and other PBL staff.	☒	
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 cooperate with and take part in team based activities.	☒	
Good basic computer skills and literacy	☒	
A desire and ability to self-improve and to improve the department.	☒	
Able to logically troubleshoot QC analysis	☒	
Able to verify QC data with a good eye for detail	☒	
Able to apply theoretical knowledge to practical situations	☒	
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:	