

## Job description

<b>Job title</b>	Senior QC Analyst
<b>Division</b>	Quality
<b>Career Level</b>	4
<b>Responsible to</b>	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<sup>®</sup> 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<sup>2</sup>)

## Person specification

	Essential	Desirable
<b>Eligibility</b>		
Current, valid Right to Work in the UK	<input checked="" type="checkbox"/>	
A good standard of written and spoken English Language	<input checked="" type="checkbox"/>	
<b>Qualification</b>		
Degree in Chemistry/Biochemistry or other suitable degree. Suitable experience may be considered as suitable	<input checked="" type="checkbox"/>	
Further degree in Chemistry, Biochemistry or equivalent discipline / membership of a scientific society.		<input checked="" type="checkbox"/>
<b>Knowledge and experience</b> Experience as defined by type/level (not length)		
Working Knowledge / Experience of cGMP	<input checked="" type="checkbox"/>	
Working Knowledge / Experience of the EP and USP	<input checked="" type="checkbox"/>	
Working Knowledge / Experience of ICH requirements.	<input checked="" type="checkbox"/>	
Previously worked in a similar laboratory as a bench analyst following written instructions and comparing analytical results with set specifications.	<input checked="" type="checkbox"/>	
Knowledge / Experience of Enzyme analysis.		<input checked="" type="checkbox"/>
Knowledge / Experience of Waters HPLC systems and associated software or equivalent		<input checked="" type="checkbox"/>
Knowledge / Experience of Gel Electrophoresis		<input checked="" type="checkbox"/>
Experience of the out of specification process and carrying out laboratory investigations	<input checked="" type="checkbox"/>	
Experience using standard analytical laboratory equipment such as pH meters, balances, pipettes.	<input checked="" type="checkbox"/>	
Knowledge / Experience using UV-Vis and FT-IR.		<input checked="" type="checkbox"/>
Knowledge / Experience using KF Moisture determination.		<input checked="" type="checkbox"/>
Knowledge / Experience analysing purified water and water for injection.		<input checked="" type="checkbox"/>
Knowledge / Experience analysing pharmaceutical raw materials		<input checked="" type="checkbox"/>
Ability to supervise junior staff and schedule workloads.	<input checked="" type="checkbox"/>	
Experienced in supervising junior staff and scheduling workloads in a similar situation		<input checked="" type="checkbox"/>
<b>Skills and capabilities</b>		
Good communication skills able to communicate technical issues clearly, both written and verbally with QC and other	<input checked="" type="checkbox"/>	

PBL staff.		
Problem solving skills and ability to respond to sudden unexpected demands.	<input checked="" type="checkbox"/>	
Ability to work on own initiative, organise own workload and prioritise daily work with minimal supervision working to tight and often changing timescales.	<input checked="" type="checkbox"/>	
Ability to use technical software packages	<input checked="" type="checkbox"/>	
Ability to cooperate with and take part in team based activities.	<input checked="" type="checkbox"/>	
Good basic computer skills and literacy	<input checked="" type="checkbox"/>	
A desire and ability to self-improve and to improve the department.	<input checked="" type="checkbox"/>	
Able to logically troubleshoot QC analysis	<input checked="" type="checkbox"/>	
Able to verify QC data with a good eye for detail	<input checked="" type="checkbox"/>	
Able to apply theoretical knowledge to practical situations	<input checked="" type="checkbox"/>	
<b>Equality and diversity</b>		
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	<input checked="" type="checkbox"/>	

Job description agreed with the post holder:

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