Job description

Job title	Senior Microbiologist
Directorate	Quality
Career Level	CL4
Responsible to	QC Microbiology 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 Bacteriology Technical Services Group is a Unit of the Quality Control (QC) Biological Services Group within Porton Biopharma Ltd, based at Porton Down, Wiltshire and supports the GMP manufacture of human Anthrax Vaccine and the anti-cancer treatment, Erwinase.

JOB SUMMARY

The purpose of this role is to provide support for the QC Microbiology department at Porton Biopharma. This will include supervising the QC Microbiology Laboratory Technologists undertaking and performing microbiological QC analyses. The role will include training and supporting laboratory techniques, and releasing QC data in support of Porton Biopharma's licensed production, service, validation and developmental programs.

We are looking for A candidate who has a high level of knowledge, understanding and practical experience of pharmaceutical microbiology. The applicant will be educated to degree level in a relevant subject or significant experience of working in a laboratory at a similar level or in a similar role. The applicant will need to demonstrate excellent communication and computer skills in addition to working with a team of microbiologists.

Communication and key working relationships

<u>Internal</u>

- First Line Manager, QC Microbiology
- Team members - QC Technologists
- Other Managers and staff in Biological Services Group
- Production Unit and Functional Managers

- Validation Technologists
- Qualified Persons
- Quality Assurance Compliance Officers
- Emcor staff

External

- The Medicines and Healthcare Regulatory Agency (MHRA) Inspectors
- Food and Drug Administration (FDA) Inspectors
- Any other regulatory inspectors
- PBL customers, contractors, suppliers

MAIN DUTIES AND RESPONSIBILITIES

- Operate in compliance in GMP and quality systems
- To test microbiological samples, working at ACDP Containment level 2 and at Containment Level 3, when required, from all stages of the production processes of products manufactured at PBL, Porton Down and to assess the results against pre-set standards.
- Supervising a small team of technologists
- Undertaking and performing microbiological QC analyses in the Quality Control Bacteriology Technical Services Unit
- Writing and reviewing of Quality Management Systems including non-conformances, change management and quality risk management
- Perform data verification of test data and results
- To record and assess results from environmental and water sampling and carry out preliminary and confirmatory identification of micro-organisms.
- To record test results clearly and accurately and perform calculations as required and to check and sign–off colleague's results and calculations.
- To safely operate, clean and maintain highly complex equipment to the required levels of cleanliness and operating standards and to record all such operations and maintenance.
- To provide cover for and assist the Environmental Monitoring team when required.
- To prepare environmental monitoring consumables for production areas in an aseptic manner on a daily basis and to pre-test this media, along with that to be used in the Unit and other areas against pre-determined standards to ensure appropriate performance.
- To maintain the culture collection, media stocks and necessary consumable supplies to ensure the efficient running of the Unit during normal production activities.
- To initiate and complete tasks requiring Change Management and Quality Risk Management in the department.
- To undertake work in accordance with the PHE Health and Safety policies and procedures and work within any Quality Systems that are applicable to the site.

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

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	☒	
A good standard of written and spoken English Language	☒	
Qualification		
Educated to degree level in relevant subject or equivalent level qualification or significant experience of working at a similar level or in a similar role	☒	☐
Knowledge and experience Experience as defined by type/level (not length)		
Significant experience of working to cGMP	☒	☐
Significant experience and knowledge of pharmaceutical Quality Assurance, EU and US GMP	☒	☐
Experience of working in a Quality Management System, and working knowledge of CAPA, change management and quality risk management	☒	☐
Knowledge and experience of microbiological testing methods, including endotoxin and bioburden testing and microbial identification	☒	☐
Relevant microbiological experience, including working at ACDP Containment Levels 2 and 3	☒	☐
Skills and capabilities		
Problem solving skills and ability to respond to sudden unexpected demands and schedule changes. Prioritisation of own work	☒	☐
Capability to plan over short and medium timeframes and adjust plans and resources accordingly	☒	☐
Good inter-personal and communication skills with stakeholders, team and managers	☒	☐
Great attention to detail, particular in regard to verification of test data and results	☒	☐
Must be prepared to work flexibly to meet the requirements of manufacturing schedules, including weekends and out of normal hours	☒	☐
Must be prepared to receive relevant vaccinations, if required	☒	
Must be able to comply with the requirements of SAPO	☒	
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:	

Manger Name:	Date:
Manager Signature:	