Job description

Job title	Senior Technologist, Bacteriology Technical Services
Directorate	Quality
Pay band	Career Level 4
Responsible to	Unit Manager, Bacteriology Technical Services
Base/location	Porton Down
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma, Porton Down has approximately 300 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The department carries out the manufacture of Erwinase and Anthrax as well as contract manufacturing projects.

The Bacteriology Technical Services Group is a Unit of the Quality Control (QC) Biological Services Group within Development & Production, based at Porton Down, Wiltshire and supports the GMP manufacture of human Anthrax Vaccine and the anti-cancer treatment, Erwinase.

JOB SUMMARY

To supervise, undertake and perform microbiological QC analyses in the Quality Control Bacteriology Technical Services Unit, which provides specialist microbiological testing services in support of licensed pharmaceutical manufacture at PBL, Porton Down, in compliance with cGMP.

Communication and key working relationships

Internal

- Unit Manager and Biological Services Manager
- 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

- To supervise and organise the workload, on a day to day basis, of the Bacteriology Technical Services Unit**.**
- 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.
- 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 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 train staff within Bacteriology Technical Services and other staff, as required.
- To write and review Standard Operating Procedures, protocols and reports in accordance with regulatory requirements.
- To complete departmental CAPAs and to implement any required quality improvements that may arise from this.
- Identify and implement quality improvements within the department pro-actively.
- 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

Description	Essential	Desirable	Assessment
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	✓		A, C
Post-graduate degree in Pharmaceutical Microbiology or relevant microbiological subject		✓	A, C
Knowledge and experience Experience as defined by type/level (not length)			
Experience of working to cGMP	✓		A, I
Knowledge and experience of microbiological testing methods, including endotoxin and bioburden testing and microbial identification	✓		A,I
Relevant microbiological experience, including working at ACDP Containment Levels 2 and 3	✓		A, I
Experience of supervision of a small team and training of staff	✓		A, I
Experience of working in a Quality Management System, and working knowledge of CAPA, change management and quality risk management	✓		
Skills and capabilities			
Problem solving skills and ability to respond to sudden unexpected demands and schedule changes. Prioritisation of own work	✓		A, I
Capability to plan over short and medium timeframes and adjust plans and resources accordingly	✓		A, I
Good inter-personal and communication skills with stakeholders, team and managers	✓		A,I

Great attention to detail, particular in regards to verification of test data and results	✓		
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	✓		A, I
Other			
Must be prepared to work flexibly to meet the requirements of manufacturing schedules, including weekends and out of normal hours	✓		A, I
Must be prepared to receive relevant vaccinations, if required	✓		I
Must be prepared to participate in out of hours, on-call rota, if required		✓	A, I
Must be able to comply with the requirements of SAPO	✓		I
***Assessment will take place with reference to the following information** **A = Application form I = Interview C = Certificate T = Test**			

Job description agreed with the post holder:

Employee signature: ……. Date:……

Print name:…….....

Manager’s signature:…….. Date:……

Print name:…….....…