Job description

Job title	QC Technician Bacteriology Technical Services
Directorate	Quality
Career Level	5
Responsible to	Unit Manager Bacteriology Technical Services
Base/location	Unit Manager Bacteriology Technical Services
Hours/sessions per week	Porton Down
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd, Porton Down has approximately 350 staff, 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 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 support the Quality Control Bacteriology Technical Services Unit, which performs specialist microbiological testing service to assist 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 - Senior QC Technologists and 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

- Ensure the environment in departmental laboratories is maintained to GMP standards of cleanliness, tidiness and audit preparedness
- Responsible for cleaning and monitoring of equipment in the department, for example:
    - Performing weekly cleaning of LAF and MSCs
    - Incubator and fridge monthly cleaning
    - Recording activities in associated logbooks
    - Reacting to alarms from temperature monitoring equipment
- Housekeeping duties to ensure the smooth running of the department, for example:
    - Preparation of cleaning reagents
    - Preparation of test reagents
    - Ordering of consumables, including media
- Maintaining stock inventories and monitor stock levels, for example
    - Microbial work cell bank/Bioball collection,
    - Media stocks via Pharmaceutical Stores
    - Consumable supplies to ensure the efficient running of the department
    - Expired reagents/media/equipment
- Decontamination and disposal of laboratory waste, for example:
    - Chemical waste disposal following local regulations
    - Ensure laboratory waste bins are emptied on a regular basis
    - Yellow sacks disposal on a regular basis
    - Ensuring disposal tins are replaced in each laboratory
- Preparation of equipment for calibration, validation, servicing and maintenance
    - Ensuring equipment is appropriately decontaminated
    - S1 completed where required
    - Recording activities in associated logbooks
- Support QC Technologists in their role in the testing of production samples, for example:
    - Incubate and reconcile environmental monitoring media plates
    - Pipetting
    - Labelling plates
    - Maintaining balance, pH meter
- GMP requirements, for example:
    - Logbook preparation and other associated GMP documentation
    - Collection and distribution of GMP documentation for QC Bacteriology
    - Ensure all documentation is completed in compliance with cGMP
    - Follow Standard Operating Procedures (SOP's) or site Quality systems
- Health & Safety
    a. To undertake work in accordance with the PBL Health and Safety policies and procedures and
    b. To work within any Quality Systems that are applicable to the site.
    c. Follow COSHH and Risk Assessments associated with the department.

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 NVQ level 3 or equivalent qualification (2 A levels) in numerate/science based subjects. Alternatively, significant experience in a similar role.	☒	☐	A,C
HNC or equivalent in a scientific discipline relevant to the post (E.g. Microbiology, Biomedical Science)	☐	☒	A,C
Knowledge and experience Experience as defined by type/level (not length)			
Experience of working within a pharmaceutical cGMP environment	☐	☒	A, I
Experience of working in a regulated environment	☐	☒	A, I
Experience of following written SOP's or GMP documentation / instructions	☒	☐	A, I
Knowledge and experience of microbiology and microbiological testing gained in a laboratory or similar environment	☐	☒	A, I
Relevant microbiological experience, including working at ACDP Containment Levels 2 and 3	☐	☒	A, I
Skills and capabilities			
Ability and willingness to learn new skills	☒	☐	A, I
Problem solving skills and ability to respond to sudden unexpected demands and schedule changes.	☐	☒	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 team and managers	☒	☐	A, I
Ability to work unsupervised to deliver tasks and objectives	☒	☐	A, I
Ability to organise personal workload, and prioritise and manage time to meet deadlines	☒	☐	A, I
Numeracy and writing skills	☒	☐	A, I
Equality and diversity			
An understanding of and commitment to equality of opportunity and good working relationships,	✓		I

both in terms of day-to-day working practices, but also in relation to management systems			
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 able to comply with SAPO requirements	☒	☐	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:…….....…