Job description

Job title	QC Technologist
Directorate	Quality
Career Level	4
Responsible to	Unit Manager, Bacteriology Technical Services, Quality Control
Base/location	Porton Down
Hours/sessions per week	37.5
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 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

To undertake and perform microbiological QC analyses in support of Porton Biopharma's licensed production, service, validation and developmental programmes.

Communication and key working relationships

Internal

- Unit Manager, Bacteriology Technical Services
- Biological Services Manager
- Production Unit and Functional Managers
- QC 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 carry out all work in compliance with cGMP
- To test microbiological samples from all stages of the production processes of licensed and developmental products and to assess the results against pre-set standards and specifications
- To undertake identification of micro-organisms isolated from microbiological tests and samples
- To record all information and data clearly and accurately
- To prepare environmental monitoring consumables for Production areas
- To pre-test media used within QC and Production against pre-set specifications
- To maintain the Bacteriology Technical Services Culture Collection, media stocks, and necessary consumables to ensure the efficient running of the group
- To safely operate, clean and maintain laboratory equipment to the required levels of cleanliness and operating standards
- To attend relevant training courses
- To work in accordance with PBL Safety Policies and Procedures
- To comply with all relevant PBL Policies and Procedures
- To perform any other duties required by the Line Manager, commensurate with grade and experience

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
Eligibility			
Right to work in the UK	☒	☐	A/I/C
A good standard of written and spoken English Language	☒	☐	A/I/C
Qualification			
HND or equivalent qualification relevant to the post	☒	☐	A/I
Degree in a scientific discipline relevant to the post	☐	☒	A/I
Knowledge and experience Experience as defined by type/level (not length)			
Knowledge and experience of microbiology gained in a laboratory or similar environment	☒	☐	A/I
Experience of working in a Good Manufacturing Practice (GMP) or similarly regulated environment	☐	☒	A/I
Skills and capabilities			
Accurate and clear record keeping and ability to work to written procedures	☒	☐	A/I
Good interpersonal skills and able to work as part of a team	☒	☐	A/I
Methodical and reliable approach to tasks and ability to think clearly	☐	☐	A/I
Ability to respond to sudden and unexpected demands and schedule changes	☒	☐	A/I
Ability and willingness to learn	☒	☐	A/I
Ability to train others	☐	☒	A/I
Must be prepared to work flexibly to meet the testing requirements of Production schedules, including outside of normal hours and at weekends. To participate in the weekend Rota to cover 7-day manufacture	☒	☐	I
Must be prepared to receive relevant vaccinations, if required	☒	☐	I
Must be able to comply with DEFRA SAPO regulations	☒	☐	I
Numeracy and writing skills	☒	☐	A/I
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	✓		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:…….....…