Job description

Job title	QC Microbiology First Line Manager
Directorate	Quality
Career Level	CL3
Responsible to	QC Microbiology Manager
Base/location	Porton
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd (PBL), 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.

JOB SUMMARY

This role will manage a team of QC Technologists and Senior QC Technologists within Development and Production and support the GMP manufacture of human Anthrax Vaccine and the anti-cancer treatment, Erwinase.

Accountable to the QC Microbiology Manager for assisting in the delivery of autonomous and innovative leadership / management.

To lead, motivate and manage one of the QC Microbiology Units, 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

- QC Microbiology Manager
- Team Members – QC Technologists and Senior QC Technologists
- Other Managers and staff in Microbiology
- Production Unit and Functional Managers

- Validation Technologists
- Qualified Persons (QP's)
- Quality Assurance Compliance Officers
- Emcor staff]

External

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

MAIN DUTIES AND RESPONSIBILITIES

- To operate in compliance with cGMP, including management of one of the QC Microbiology Units facilities and equipment.
- To manage, lead and motivate one of the QC Microbiology Units in the planning, resource management, direction and performance of specialist microbiological analyses and testing to regulatory/customer requirements to support pharmaceutical manufacture.
- To recognise and play a lead role with internal and external customers in the development of novel microbiological techniques in support of project requirements, regulatory requirements and business needs.
- To support PBL, Porton Down in performance of validation programmes to meet regulatory/customer requirements.
- To take and maintain a lead role in the preparation, approval and maintenance of procedures, protocols and reports in accordance with customer requirements and regulatory needs.
- To provide specialist training to one of the QC Microbiology Units and also to personnel involved in GMP manufacturing activities at PBL, Porton Down, if required.
- To maintain up to date awareness of regulatory and scientific advances by attending training courses and meetings that contribute to the efficiency and effectiveness of staff training and working practices that are beneficial to the post holders development.
- To suggest and implement changes to work practices/procedures within the framework of regulations.
- To undertake work in accordance with the Porton Down site Health and Safety policies and procedures and work within any Quality Systems that are applicable to the site.
- To deputise for the QC Microbiology Manager, when required.

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 in specialist area	☒	☐	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, bioburden, water testing and microbial identification	☒	☐	A,I
Relevant microbiological experience, including working at ACDP Containment Levels 2 and 3	☒	☐	A,I
Experience of management of a small team and training of staff	☒	☐	A,I
Skills and capabilities			
Problem solving skills and ability to respond to sudden unexpected demands and schedule changes. Prioritization 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
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	☒	☐	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:…….....…