Job description

Job title	QC Microbiology First Line Manager
Division	Quality
Career Level	3
Responsible to	QC Microbiology Manager

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range development and manufacturing roles for biopharmaceuticals. This also includes all associated support functions from logistics through to engineering, quality control / quality assurance, regulatory affairs and management. The Company manufactures two licensed products, Erwinase® and the UK's Anthrax Vaccine as well as providing R&D services for product development.

The Quality Control Microbiology group supports the GMP manufacture of Human Anthrax Vaccine and the anti-cancer treatment, Erwinase®. The QC Microbiology dept. is responsible for the environmental monitoring program across manufacturing including aseptic filling, the QC Microbiology laboratories performing analysis in line with cGMP and maintaining validated compliant methods.

JOB SUMMARY

This role will manage a team of QC Microbiologists and Senior QC Microbiologists 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

<u>Internal</u>

- QC Microbiology Manager
- Head of Quality Control
- Team Members – QC Technicians, 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, USP, EP, BP, JP, In-house, FDA and MHRA regulatory requirements, 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 manage the timely release of QC Microbiology results.
- To lead HSE, internal and external audits including those by regulatory agencies.
- 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 lead continuous improvement activities of the laboratories.
- 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.

You should adhere PBL values and behaviors:

- Passion
- Respect
- Integrity
- Diligence
- Excellence in Execution (E^2)

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 in specialist area	☒	☐
Post-graduate degree in Pharmaceutical Microbiology or relevant microbiological subject	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Experience of working to cGMP, USP, EP and FDA and MHRA regulatory guidance documents.	☒	☐
Knowledge and experience of microbiological testing methods, including endotoxin, bioburden, sterility, water testing and microbial identification.	☒	☐
Relevant microbiological experience, including working at ACDP Containment Levels 2	☒	☐
Experience of management of a team and training of staff	☒	☐
Experience of environmental monitoring	☐	☒
Experience using LIMS	☐	☒
Skills and capabilities		
Problem solving skills and ability to respond to sudden unexpected demands and schedule changes. Prioritization 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	☒	☐
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:	

Manager Name:	Date:
Manager Signature:	