Job description

Job title	QC Microbiology Manager
Directorate	Quality
Career Level	CL2
Responsible to	Head of Quality Operations
Base/location	Porton
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.

This role will manage a team of First Line Managers within Development and Production, based at Porton Down, Wiltshire and supports the GMP manufacture of human Anthrax Vaccine and the anti-cancer treatment, Erwinase®.

JOB SUMMARY

Accountable for leading a team to secure delivery of:

- The development of more public health interventions in shorter timescales.
- A reduction in regulatory hurdles in the development and release of existing and new products
- The targets and objectives agreed with line management.
- Specialist advice and represent PBL during regulatory and customer audits.

Accountable to the Head of Quality Operations for assisting in the delivery of autonomous and innovative leadership / management.

To provide leadership and QC management of the microbiology department.

To monitor performance of the QMS in place.

To provide leadership, communication and expertise to continuously improve microbiology compliance across PBL.

Communication and key working relationships

Internal

- Senior Quality Managers and other Senior Managers
- PBL staff across all levels

External

- National and International customers and suppliers
- Regulatory Inspectors

MAIN DUTIES AND RESPONSIBILITIES

- To work with other managers within the Quality team to ensure that manufacturing and quality activities are performed in compliance with all the regulations and other requirements including: the Rules & Guidance for Pharmaceutical Manufacturers' and Distributors, cGMP guidance, and other regulations governing PBL activities.

- To lead projects and deliver required outcomes in own specialist area.

- To lead, motivate, coach, mentor and manage the performance and output of the Microbiology Team (including direct managerial reports) and ensure that all team objectives are met in agreed timescales.

- To maintain and develop the local standard operating procedures to secure effective working practices as well as compliance with relevant national, European and US legislation.

- Monitor the performance of the systems under area of responsibility using KPIs and report to management.

- Develop and implement an ongoing Quality Improvement Plan related to the systems under area of responsibility

- To lead the development and implementation of an ongoing Health & Safety Plan for the team to secure the right level of performance, highlight failures and make recommendations for solutions.

- In line with overall responsibilities, perform additional tasks assigned by the line manager.

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.

PORTON BIOPHARMA

Person specification

Description	Essential	Desirable	Assessment
Qualification			
Educated to degree level or equivalent in appropriate scientific discipline	☒	☐	A/I
Post-graduate degree in life /applied science or equivalent	☐	☒	A/I
Member of appropriate professional body	☐	☒	A
Experience in sterile manufacture	☐	☒	A/I
Experience with biologics	☐	☒	A/I
Proven track record of leadership	☐	☒	A/I
Knowledge and experience Experience as defined by type/level (not length)			
Trained microbiologist	☒	☐	A/I
Significant experience of managing teams	☒	☐	A/I
Experience of operating and managing quality systems for compliance to regulatory requirements (e.g. batch release, non-conformance, risk management) and a focus on continuous improvement.	☒	☐	A/I
Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction	☒	☐	A/I
Substantial practical experience within a GMP environment, particularly in the context of biologics and steriles manufacture.	☒	☐	A/I
Knowledge and experience of Aseptic Manufacture	☒	☐	A/I
Must have operational knowledge of EU/US pharmaceutical regulatory requirements, particularly for biologics and sterile products.	☒	☐	A/I
Skills and capabilities			
Programme and project management corporate awareness	☒	☐	A/I
Service delivery and improvement	☒	☐	A/I
Communication and stakeholder relations	☒	☐	A/I

Financial and commercial management	☒	☐	A/I
Staff management	☒	☐	A/I
Must be able to provide and receive highly complex, sensitive or contentious information, negotiate with senior stakeholders on difficult and controversial issues and present complex and sensitive information to large and influential groups	☒	☐	A/I
Must have problem solving skills and the capability to respond to sudden unexpected demands	☒	☐	A/I
Must be capable of identifying potential product impact from the analysis of adverse events.	☒	☐	A/I
Must have the capacity to obtain process and product knowledge required to provide advice to Operational teams and to respond to adverse events	☒	☐	A/I
Must be able to prioritise own work and direct the activities of others effectively. Experience of managing and motivating a team and reviewing the performance of individuals	☒	☐	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
Other			
Must be prepared to meet the requirements of manufacturing schedules which may include working out of hours and weekends.	☒	☐	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:…….....…