

## Job description

<b>Job title</b>	QC Microbiology Manager
<b>Directorate</b>	Quality
<b>Career Level</b>	2
<b>Responsible to</b>	Head of Quality Operations
<b>Base/location</b>	Porton
<b>Hours/sessions per week</b>	37.5
<b>Job type</b>	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<sup>®</sup> and Anthrax Vaccine as well as contract manufacturing projects.

This role will manage a team of First Line Managers within Development and Production and support the GMP manufacture of Human Anthrax Vaccine and the anti-cancer treatment, Erwinase<sup>®</sup>.

### 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.



# Person specification

Description	Essential	Desirable	Assessment
<b>Qualification</b>			
Educated to degree level or equivalent in appropriate scientific discipline	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Post-graduate degree in life /applied science or equivalent	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Member of appropriate professional body	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A
Experience in sterile manufacture	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Experience with biologics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Proven track record of leadership	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
<b>Knowledge and experience</b> Experience as defined by type/level (not length)			
Trained microbiologist	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Significant experience of managing teams	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Substantial practical experience within a GMP environment, particularly in the context of biologics and steriles manufacture.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Knowledge and experience of Aseptic Manufacture	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Must have operational knowledge of EU/US pharmaceutical regulatory requirements, particularly for biologics and sterile products.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
<b>Skills and capabilities</b>			
Programme and project management corporate awareness	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Service delivery and improvement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Communication and stakeholder relations	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Financial and commercial management	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Staff management	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Must have problem solving skills and the capability to	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I

respond to sudden unexpected demands			
Must be capable of identifying potential product impact from the analysis of adverse events.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
<b>Equality and diversity</b>			
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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	I
<b>Other</b>			
Must be prepared to meet the requirements of manufacturing schedules which may include working out of hours and weekends.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A,I
Must be prepared to receive relevant vaccinations, if required	<input checked="" type="checkbox"/>	<input type="checkbox"/>	I
Must be prepared to participate in out of hours, on-call rota, if required	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A,I
Must be able to comply with the requirements of SAPO	<input type="checkbox"/>	<input checked="" type="checkbox"/>	I
<b>*Assessment will take place with reference to the following information</b>			
<b>A = Application form                      I = Interview                      C = Certificate                      T = Test</b>			

Job description agreed with the post holder:

Employee signature: ..... Date:.....

Print name:.....

Manager's signature:..... Date:.....

Print name:.....