Job description

Job title	QC Microbiology Manager
Division	Quality
Career Level	2
Responsible to	Head of Quality Control

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized company 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 the Quality Control Microbiology group and support the GMP manufacture of Human Anthrax Vaccine and the anti-cancer treatment, Erwinase®. The QC Microbiology manager is responsible for the environmental monitoring program across manufacturing including aseptic filling and the QC Microbiology laboratories performing analysis in line with cGMP.

JOB SUMMARY

To lead and manage the QC Microbiology department including the environmental monitoring program, laboratory testing to cGMP, ensuring compliance with regulatory requirements and developing and fulfilling a continuous improvement program.

Communication and key working relationships

Internal

- Head of Quality Control
- Director of Quality
- Production Managers
- Biological Services QC Manager
- Qualified Person(s)
- Validation Manager
- Analytical Method Development Manager
- Regulatory Affairs
- Project Managers
- Capital Projects

External

- MHRA (Medicines and Healthcare Regulatory Agency)
- Department of Health (DH)
- Department for Environment, Food and Rural Affairs (DEFRA)
- National Institute for Biological Standards and Control (NIBSC)
- Commercial customers
- Food and Drug Administration (FDA)
- Any other regulators as required

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.
- Oversight and responsibility for the environmental monitoring program in manufacturing areas in line with industry guidance.
- Oversight and responsibility for all laboratory activities in line with the Ph. Eur and USP.
- Leading regulatory audits of the QC Microbiology group including regulatory audits, internal audits and customer audits and contructing audit responses
- Providing Microbiology expertise in investigations, reviewing investigations and writing detailed investigation reports on any major issues.
- Writing, reviewing and tracking change controls, deviations and laboratory investigations where required.
- Ensuring all departmental KPIs are met.
- To recruit staff and to plan staff development succession planning to meet current and future needs of the process and production.
- To ensure sufficiently trained staff are in place to carry out the testing and supervision of the testing, procedures and equipment.
- To lead the training, management, appraisal and mentoring of staff to ensure performance, safety and training standards are achieved.

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)

PORTON BIOPHARMA

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 or equivalent in appropriate scientific discipline	☒	☐
Post-graduate degree in life /applied science or equivalent	☐	☒
Member of appropriate professional body	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Trained microbiologist	☒	☐
Significant experience of managing teams	☒	☐
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.	☒	☐
Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction	☒	☐
Substantial practical experience within a GMP environment,	☒	☐

particularly in the context of biologics and steriles manufacture.		
Knowledge and experience of Aseptic Manufacture	☒	☐
Knowledge of EU/US pharmaceutical regulatory requirements, for biologics and sterile products.	☒	☐
Experience in sterile manufacture	☐	☒
Experience with biologics	☐	☒
Proven track record of leadership	☒	☐
Skills and capabilities		
Programme and project management corporate awareness	☒	☐
Service delivery and continuous improvement	☒	☐
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 a large and influential groups. Ability to negotiate on difficult and controversial issues including performance and change.	☒	☐
Previously involved in budget. Involved in budget setting and working knowledge of financial processes.	☐	☒
Must be able to prioritise own work effectively and be able to direct activities of others. Experience of managing and motivating a team and reviewing performance of an individual.	☒	☐
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	☒	☐
Must have problem solving skills and the capability to respond to sudden unexpected demands	☒	☐
Must be capable of identifying potential product impact from the analysis of adverse events.	☒	☐
Must have the capacity to obtain process and product knowledge required to provide advice to Operational teams and to respond to adverse events	☒	☐
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	☒	☐
Must be prepared to meet the requirements of manufacturing schedules which may include working out of hours and weekends.	☒	☐
Must be prepared to receive relevant vaccinations, if required	☒	☐
Must be prepared to participate in out of hours, on-call rota, if required	☒	☐
Must be able to comply with the requirements of SAPO	☐	☒
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:	