



Job description

Job title	Senior Microbiologist (EM)
Division	Quality
Career Level	CL4
Responsible to	QC Microbiology First Line 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 Environmental Monitoring Team is a Unit of the Quality Control (QC) Biological Services Group within Porton Biopharma Ltd, based at Porton Down, Wiltshire and supports the GMP manufacture of human Anthrax Vaccine and the anti-cancer treatment, Erwinase.

JOB SUMMARY

The purpose of this role is to provide support for the QC Environmental Monitoring Team at Porton Biopharma. This will include supervising junior analysts undertaking and performing environmental monitoring throughout the Production facilities on-site. The role will include training and supporting new and existing staff members, and releasing QC data in support of Porton Biopharma's licensed production, service, validation and developmental programs.

We are looking for A candidate who has a high level of knowledge, understanding and practical experience of pharmaceutical microbiology. The applicant will be educated to degree level in a relevant subject or significant experience of working in a laboratory at a similar level or in a similar role. The applicant will need to demonstrate excellent communication and computer skills in addition to working with a team of environmental monitoring analysts.

Communication and key working relationships

Internal

- First Line Manager, QC Microbiology
- Team members – Environmental Monitoring Analysts
- Team members - QC Technologists
- Other Managers and staff in Biological Services Group
- Production Unit and Functional Managers
- Validation Technologists
- Qualified Persons
- Quality Assurance Compliance Officers
- Emcor staff

External

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

MAIN DUTIES AND RESPONSIBILITIES

- Operate in compliance in GMP and quality systems.
- To conduct environmental monitoring in the Erwinase production facility and the Anthrax vaccine facility.
- Supervising junior members of staff.
- Trending of EM data.
- Writing and reviewing of Quality Management Systems including non-conformances, change management and quality risk management.
- Perform data verification of test data and results.
- To assess results from environmental and water sampling.
- Write, review and discuss batch related summary reports.
- To initiate and complete tasks requiring Change Management and Quality Risk Management in the department.
- To undertake work in accordance with the PHE Health and Safety policies and procedures and work within any Quality Systems that are applicable to the site.
- Train new and existing members of staff in environmental monitoring and related techniques.

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 (E²)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	<input checked="" type="checkbox"/>	
A good standard of written and spoken English Language	<input checked="" type="checkbox"/>	
Qualification		
Educated to degree level in relevant subject or equivalent level qualification or significant experience of working at a similar level or in a similar role.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Knowledge and experience Experience as defined by type/level (not length)		
Significant experience of working to cGMP	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Significant experience and knowledge of pharmaceutical Quality Assurance, EU and US GMP	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Experience of working in a Quality Management System, and working knowledge of CAPA, change management and quality risk management	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Knowledge and experience of microbiological testing methods, including endotoxin and bioburden testing and microbial identification	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Relevant microbiological experience, including working at ACDP Containment Levels 2 and 3	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Skills and capabilities		
Problem solving skills and ability to respond to sudden unexpected demands and schedule changes. Prioritisation of own work	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Capability to plan over short and medium timeframes and adjust plans and resources accordingly	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Good inter-personal and communication skills with stakeholders, team and managers	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Great attention to detail, particular in regard to verification of test data and results	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Must be prepared to work flexibly to meet the requirements of manufacturing schedules, including weekends and out of normal hours	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Must be prepared to receive relevant vaccinations, if required	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Must be able to comply with the requirements of SAPO	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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	<input checked="" type="checkbox"/>	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	