# Job description

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

**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.

The Environmental Monitoring Team is part of the Quality Control (QC) Biological Services Group within Porton Biopharma, based at Porton Down, Wiltshire. The group provides Quality Control services to support the GMP manufacture of pharmaceutical products.

**JOB SUMMARY**

Accountable to the Pharmaceutical Microbiologist for assisting in the delivery of autonomous and innovative leadership/management.

To lead the Environmental Monitoring Team and to maintain a high level of support and EM training across site to all functions. To provide specialist training in microbiological environmental monitoring methods and water sampling, and to undertake the microbiological environmental monitoring of critical pharmaceutical manufacturing operations. To supervise, oversee, observe and qualify all production technologists and other staff where applicable, in gowning, microbiological environmental monitoring methods and water sampling.

**Communication and key working relationships**

Internal

- Senior Quality Leadership
- QC Microbiology Manager
- Pharmaceutical Microbiologist
- First Line Managers
- Members of the site services team
- New starters requiring training
- QC Compliance officers

- QC Administrators
- QC Technologists and Senior Technologists (Monitoring and Training)
- Validation Technologists
- Emcor Staff

External

- PBL Customers, contractors and suppliers
- Regulatory inspectors

**MAIN DUTIES AND RESPONSIBILITIES**

- Lead, motivate and manage the performance and output of the EM Team to ensure that the team objectives are met in a timely manner.
- Identify and implement improvements to the sitewide EM programme.
- Maintain training levels across site to the highest standard for EM and compliance.
- Monitor, schedule and ensure efficient throughput of Environmental Monitoring and Water data.
- Plan and organize schedules for EM Team to ensure adequate assistance is provided to support critical manufacturing processes.
- Escalate, troubleshoot and provide solutions to any unexpected issues arising in the laboratory or during EM.
- Perform monthly one-to-one meetings with team members, provide support and monitor their progression against set objectives.
- Be involved in writing and updating standard operating procedures relating to environmental monitoring and water sampling.
- Conduct investigations, initiate and execute CAPAs and Compliance Action Items in a timely manner. Additionally, generate, write and perform technical review/ approval of EM and validation reports, and result summaries
- Attend training courses that contribute to the efficiency of the operating systems and are beneficial to the post holder's personal development.
- Coach and support QC staff by assisting in training and qualifying all production and other staff, as necessary in the techniques and procedures for microbiological environmental monitoring and water sampling.
- Support QC staff in carrying out environmental monitoring for critical manufacturing operations.
- Undertake all work in accordance with Porton Down's Code of safety practice and quality systems.
- Operate in compliance with SOPs, c/GMPs and other regulatory requirements.
- Execute EM testing if required.
- Support microbiological testing and result review/ verification if 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 organization.

**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
- etc.

# Person specification

| | Essential | Desirable |
|---|---|---|
| **Eligibility** | | |
| Current, valid Right to Work in the UK | ☒ | |
| A good standard of written and spoken English Language | ☒ | |
| **Qualification** | | |
| Degree in a scientific discipline relevant to the post | ☒ | ☐ |
| Post-graduate degree in Pharmaceutical Microbiology or relevant life science subject | ☐ | ☒ |
| **Knowledge and experience**<br>Experience as defined by type/level (not length) | | |
| Experience of working in a pharmaceutical GMP or similar regulated environment | ☒ | ☐ |
| Experience and good knowledge of Environmental Monitoring | ☒ | ☐ |
| Experience of leading a team, project, and training of staff | ☒ | ☐ |
| **Skills and capabilities** | | |
| Team player | ☒ | ☐ |
| Experience of working in a cleanroom | ☒ | ☐ |
| Experience of working in a QC laboratory | ☒ | ☐ |
| Experience of GMP or similar documentation systems | ☒ | ☐ |
| Experience of microbiology, hygiene, aseptic practices and contamination control | ☒ | ☐ |
| Microsoft Office skills, particularly Excel, Outlook and Word | ☒ | ☐ |
| Experience of Aseptic Manufacture | ☒ | ☐ |
| 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 | ☒ | ☐ |
| Attention to details and good review skills | ☒ | ☐ |
| Good writing skills; able to write reports and summaries | ☒ | ☐ |
| 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:

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| Employee Name: | Date: |
| Employee Signature: | |

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|---|---|
| Manager Name: | Date: |
| Manager Signature: | |