Job description

Job title	QC Technologist (Monitoring and Training)
Directorate	Biological Services, Quality Control
Career Level	4
Responsible to	QC Environmental Monitoring Team Leader
Base/location	Porton Down
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma, 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 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

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

- QC Microbiology Manager
- QC Technologists and Senior Technologists (Monitoring and Training)
- First Line Managers
- Members of the GMP Engineering team
- Members of the Site Services team
- New starters requiring training
- QC Compliance Officers
- QC Administrators
- Validation Technologists

- Emcor staff

External

- PBL customers, contractors, suppliers
- Regulatory Inspectors authorities

MAIN DUTIES AND RESPONSIBILITIES

- Operate in compliance with cGMP.
- Train and qualify all Production and other staff, as necessary, in the techniques and procedures for microbiological environmental monitoring.
- Train and qualify all Production and other staff, as necessary, in water sampling.
- Train and qualify all Production and other staff, as necessary, in procedures for gowning.
- Oversee, supervise and observe Production and other staff undertaking environmental monitoring and water sampling to ensure continued compliance.
- Re-qualify Production and other staff at a defined frequency, as required by GMP.
- Plan and organise schedules for training, qualifications and observations.
- Assess staff competence in environmental monitoring, water sampling and gowning procedures. Sign training documentation and produce certificates for trained members of staff.
- Carry out and record microbiological environmental monitoring for critical manufacturing operations, and routine monitoring where required.
- Input microbiological environmental monitoring and water sampling data into appropriate databases and spreadsheets.
- Be involved in the writing and updating of Standard Operating Procedures relating to environmental monitoring and water sampling, either as the author, or by providing technical information and advice to the author.
- Attend training courses that contribute to the efficiency of the operating systems and are beneficial to the post holder's personal development.
- Follow operating procedures at all times and ask for advice when necessary.
- Undertake all work in accordance with Porton Down's Code of Safety Practice and Quality Systems.
- To prepare environmental summary reports of production processes for insertion into documents, reports and batch manufacturing records as part of batch release.
- To investigate out-of-specification water and environmental monitoring test results in conjunction with the Compliance Team and review resulting Non-Conformances, participating in Ishikawa and 5-Whys investigations, where necessary.

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 post holder must hold a current valid right to work in the UK.

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
Qualification			
Degree in a scientific discipline relevant to the post or equivalent previous experience	☒	☐	A,C
Equivalent experience relevant to the post	☒	☐	A,C, I
Knowledge and experience Experience as defined by type/level (not length)			
Experience of working to cGMP or similar regulated environment and completion of GMP documentation	☒	☐	A, I
Experience of environmental monitoring/sampling	☒	☐	A, I
Skills and capabilities			
Supervisory and training experience	☐	☒	A, I
Experience of working in a cleanroom and gowning practices	☒	☐	A, I
Experience of working in a QC laboratory	☐	☒	A, I
Knowledge of basic Microbiology, hygiene, aseptic practices and contamination control	☒	☐	A, I
Knowledge and experience using Microsoft Office skills, particularly Excel, Outlook and Word.	☒	☐	A, I
Experience of aseptic manufacture	☐	☒	A, I

Good interpersonal skills and able to work as part of a team, as well as alone	☒	☐	A, I
Ability to work to deadlines and prioritize workload effectively	☒	☐	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
Additional Requirements			
Must be prepared to receive relevant vaccinations, if required	☒	☐	I
Must be able to comply with DEFRA SAPO regulations	☒	☐	I
Must be prepared to work flexibly to meet the requirements of Production schedules, including out of hours and weekends	☒	☐	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:…….....…