Job description

Job title	Environmental Monitoring Compliance Officer
Directorate	Biological Services, Quality Control
Career Level	4
Responsible to	Pharmaceutical Microbiologist
Base/location	Porton Down
Hours/sessions per week	37.5
Job type	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® 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 and supports the GMP manufacture of human Anthrax Vaccine and the anti-cancer treatment, Erwinase.

JOB SUMMARY

The post holder will be part of the QC Environmental Monitoring team and assist with activities that includes the following:

- Managing the GMP databases for water quality, clean steam quality and microbiological environmental monitoring.
- Co-ordinate and review water quality, clean steam quality and microbiological environmental monitoring activities as required.
- Preparing and analysing technical and numerical information from the databases and preparing trend analysis data as graphs, charts and / or diagrams.
- Investigating OOS water and environmental monitoring test results and reviewing resulting Non-Conformances.
- Preparing environmental summary reports of production batches and process simulations for inclusion in the batch manufacturing records.
- Reviewing particle monitoring data from the manufacturing areas.
- Reviewing and managing the environmental monitoring SOPs.

- Liaising with production, quality and engineering services to promote GMP compliance. Reviewing facility, utility and equipment documentation and monitoring data to prepare facility release reports.
- Carrying out facility release and other internal and external audits

Communication and key working relationships

Internal

- Biological Services Manager
- Pharmaceutical Microbiologist
- Production Unit and Functional Managers
- Validation
- QA
- Facilities Management
- Engineering
- Qualified Persons

External

- Commercial customers
- Consultants
- Regulatory authorities
- Suppliers
- Testing houses.

MAIN DUTIES AND RESPONSIBILITIES

1. To assist as a member of the QC Environmental Monitoring Team effectively to achieve the team objectives.

2. To liaise with internal customers, production staff, operational project management, and other quality staff to promote compliance with GMP and customer requirements and act as a Subject Matter Expert during regulatory and customer audits.

3. To co-ordinate and review water quality, clean steam quality, and microbiological and non-viable environmental monitoring activities, as required. To prepare trend analysis data as graphs, charts and / or diagrams as required.

4. 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.

5. To be a member of the Environmental Monitoring Team, Sterility Assurance Program Board and Water Quality Group, attending meetings and completion of actions as required.

6. To generate the water monitoring schedule.

7. To review and process, where required, CAPAs, Change Controls, Validation Documentation, GMP Engineering testing reports and sign off as QC reviewer, where applicable.

8. To prepare environmental summary reports and Product Quality Reviews of production processes for insertion into documents, reports and batch manufacturing records as part of batch release.

9. To review the environmental monitoring SOPs for each production area in conjunction with QA and Production.

10. To participate in facility release and other internal and external audits, as required.

11. To review facility, utility and equipment documentation, monitoring data and validation / calibration data and review summary reports for facility release purposes.

12. To carry out smoke visualisation testing as part of a multidisciplinary team including members of QA, Production and GMP Engineering in order to identify appropriate environmental monitoring sites.

13. To carry out oversight duties in manufacturing areas, record findings and communicate to the Line Manager and QA.

14. To undertake relevant training.

15. To undertake work in accordance with the PBL's Health and Safety policies and procedures and to work within any Quality Systems that are applicable to the site.

16. To comply with PBL policies and procedures.

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
Qualification			
Degree or equivalent in microbiology, chemistry or pharmacy	☒	☐	A, I, C
Knowledge and experience Experience as defined by type/level (not length)			
Significant relevant work experience in a GMP regulated environment.	☒	☐	A, I
Significant work experience and knowledge of pharmaceutical Quality Assurance, EU and US GMP.	☐	☒	A, I
Experience of pharmaceutical manufacture	☐	☒	
Experience of environmental monitoring techniques	☐	☒	
Experience of pharmaceutical water systems	☐	☒	
Skills and capabilities			
Ability to work with minimal supervision and to strict deadlines	☒	☐	A, I
Ability to work methodically and to a high degree of accuracy	☒	☐	A, I
Capable of working effectively as part of a team	☒	☐	
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
***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:…….....…