PORTON BIOPHARMA

# Job description

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|---|---|
| **Job title** | Cleaning Validation Technologist |
| **Directorate** | Engineering: Validation |
| **Career Level** | 3 |
| **Responsible to** | Cleaning Validation Lead |
| **Base/location** | Porton Biopharma Porton Down |
| **Hours/sessions per week** | 37.5 |
| **Job type** | Validation: Technical and Supervisory |

## INTRODUCTION

Porton Biopharma Ltd, Porton Down has approximately 300 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The department carries out the manufacture of Erwinase® and Anthrax Vaccine as well as contract manufacturing projects.

The Cleaning Validation team within the Validation Department supports the development and validation/qualification of manufacturing equipment cleaning processes. This includes both the validation of new or amended cleaning processes, and the ongoing routine cleaning verification of existing and validated cleaning processes.

## JOB SUMMARY

This role is to execute the timely completion of cleaning validation studies in support of PBL manufacturing activities and regulatory requirements. The role will include the writing, review and execution of cleaning validation/verification protocol documents and reports, the coordination of support activities and resources to deliver on time a high standard of documentation.

The position holder will be expected to attend project group meetings, liaise with PBL support teams and peers to establish data for inclusion within protocols and reports.

The position holder should be prepared to execute and witness cleaning validation/verification studies in line with the Production schedule.

There will be a requirement to support other validation activities (e.g. Process Validation) on a temporary basis

**Communication and key working relationships**

Internal

- Validation Manager
- Cleaning Validation Lead
- Validation Team
- Project Managers
- Technical Support
- Senior Management
- Quality Control
- Quality Assurance

External

- Regulatory agency representatives during inspections
- Contract laboratories
- Equipment vendors

**MAIN DUTIES AND RESPONSIBILITIES**

- Write, review and execute cleaning validation/verification protocol documents.
- Write cleaning validation/verification reports, where required.
- Write, review and execute cleaning development documentation.
- Deliver assigned cleaning development, validation and verification activities on time in accordance with the Site Validation Master Plan (VMP).
- To deliver on non-conformance, action item, change control (CC) and CC actions on time.
- Participate in assigned GEMBA meetings/activities, as 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 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.

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# Person specification

| Description | Essential | Desirable | Assessment |
|---|---|---|---|
| **Qualification** | | | |
| Degree or higher education qualifications in a science or engineering discipline | ☒ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| **Knowledge and experience**<br>Experience as defined by type/level (not length) | | | |
| Experience within the pharmaceutical or biopharma industry | ☒ | ☐ | |
| Experience within a Cleaning Validation role | ☒ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| **Skills and capabilities** | | | |
| Competent PC skills, including Microsoft Word and Excel software | ☒ | ☐ | |
| Demonstrated skills and capability in planning, preparing, executing and reporting of validation activities | ☒ | ☐ | |
| Cross-functional communication skills | ☐ | ☒ | |
| Awareness of Lean Manufacturing techniques | ☐ | ☒ | |
| | ☐ | ☐ | |
| **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:.....