Job description

Job title	Validation Technologist – Facilities and Utilities
Directorate	Engineering: Validation
Career Level	3
Responsible to	Process Equipment and Facility Team Leader
Base/location	Porton Biopharma, 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.

JOB SUMMARY

The Facilities Validation department supports cGMP manufacturing activities and is responsible for ensuring compliance to the cGMP guidelines on Validation activities.
The purpose of this role is to execute validation activities relating to Facilities and Utilities. This will involve coordination with Engineering, Production, QC and QA departments to ensure a timely delivery of the qualification report.
The post holder may be expected to supervise contractor resource where appropriate with responsibility to ensure adequate training and supervision is provided.

The post holder will be required to write, review and where appropriate approve validation reports prior to execution, followed by report generation. The core activities will include thermal and microbiological testing of:

- Autoclaves (BSEN 285)
- Depyrogenation ovens
- Extraction Tanks
- Centrifuges
- Vessels
- (but not limited to) the qualification of Facilities and Utilities

In addition to Utilities and Sterilisation validation activities the post holder will be expected to undertake any related validation activities deemed necessary by line management. This could include the generation of validation documentation in accordance with the full validation life cycle for equipment, utilities and facilities

Communication and key working relationships

Internal

- Validation program manager
- Project managers
- Technical support
- Senior management
- Production and Quality Assurance
- Engineering (EMCOR)
- Safety

External

- Regulatory agencies during audits MHRA and FDA
- Customers
- Suppliers (technical support)
- Contractors

MAIN DUTIES AND RESPONSIBILITIES

- Generate, review (technical) and execute process validation protocols (thermal and microbiological testing)
- Create Process validation reports
- Using the Electronic Quality Management System (master control) to manage appropriate corrective action plans and report through the PBL non-conformance system, for failures/performance issues.
- Write and review Risk assessments
- Manage work schedule as planned by the validation schedule co-ordinator
- Coordinate Contractor or permanent resources to deliver timely documentation in support of Process Validation activities
- Ensure Process Validation procedures are aligned with regulatory requirements
- Meet all internal regulatory training requirements (internal training provided)

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
Eligibility			
Current, valid Right to Work in the UK	☒	☐	A/I
Qualification			
Degree or equivalent Higher Education qualifications	☒	☐	A/C
Knowledge and experience Experience as defined by type/level (not length)			
Significant proven experience of Validation	☐	☒	A/I
Biologicals Pharma experience	☐	☒	A/I
BSEN-285 - Sterilisation. Steam sterilisers. Large sterilisers	☐	☒	A/I
Orange Guide - Rules and Guidance for Pharmaceutical Manufacturers and Distributors	☐	☒	A/I
Datalogger (V2K) and Val Probe equipment and software	☐	☒	A/I
Skills and capabilities			
Word, Excel, Access experience	☒	☐	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

***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:…….....…