Job description

Job title	Validation Technologist
Division	Engineering
Career Level	3
Responsible to	Process Equipment and Facility Team Leader

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 Validation team comprises of approximately 30 specialists on a permanent or contractual basis. The scope of Validation activities for the team covers general re-qualification of equipment, facilities and utilities with an experienced knowledge base of Computer System Validation, Cleaning Validation, Process Validation and the delivery of capital equipment into beneficial use.

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 Equipment (Process and Sterilisation), Facilities and Utilities. This will involve coordination with Engineering, Production, QC and QA departments to ensure a timely delivery of the qualification activities and documentation.
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 protocols prior to execution, followed by report generation. The core activities will include qualification of:

- Autoclaves (BSEN 285)
- Depyrogenation ovens
- Extraction Tanks
- Centrifuges
- Vessels
- Facilities and Utilities

Communication and key working relationships

Internal

- Validation manager
- Project managers
- Technical support
- Senior management
- Production and Quality Assurance
- Engineering
- Safety

External

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

MAIN DUTIES AND RESPONSIBILITIES

- Generate, review (technical) and execute validation protocols
- Create 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 validation activities
- Ensure 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.

You should adhere PBL values and behaviors:

- Passion
- Respect
- Integrity
- Diligence

- Excellence in Execution (E^2)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	☒	
A good standard of written and spoken English Language	☒	
Qualification		
Degree or equivalent higher educational qualifications	☒	☐
Knowledge and experience Experience as defined by type/level (not length)		
Hands-on experience of validation	☒	☐
Biopharmaceutical experience	☐	☒
BSEN-285 – Sterilisation, steam sterilisers, large sterilisers.	☐	☒
Understanding of the validation life cycle.	☒	☐
Facilities and utilities validation.	☐	☒
Equipment validation.	☒	☐
Risk based approach to validation.	☐	☒
Datalogger (V2K) and Val Probe equipment and software.	☐	☒
Demonstrated skills and capability in planning, preparing, executing and reporting of validation activities.	☒	☐
Skills and capabilities		
Word, Excel etc	☒	☐
Corss functional communication skills	☐	☒
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:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	