Job description

Job title	Equipment Validation Manager
Directorate	Engineering : Validation
Pay band	Level 2
Responsible to	Validation Program Manager
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 business carries out the manufacture of Erwinase and Anthrax Vaccine as well as contract manufacturing projects.

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JOB SUMMARY

This is a pivotal role within the Validation team requiring both technical and managerial skills.

This role is to lead, coordinate and manage the timely delivery of validation activities for Equipment and systems in support of PBL Operational activities and Regulatory requirements. The role will include the management of resources to complete the timely execution of Equipment validation protocols and reports,

The position holder will be responsible for the management of permanent and contractor resources, their development, supervision, training and safety.

The position holder will be expected to attend project group meetings, review and approve documentation, liaise with PBL technical and managerial staff, regulatory bodies and peers to establish appropriate resources to effect the timely and accurate execution of Validation activities.

The scope of validation activities will include (not exclusively) Cleaning validation, Minor Equipment prospective validation, requalification activities for equipment, utilities and facilities.

Communication and key working relationships

Internal

- Validation program manager
- Project managers
- Technical support
- Senior management

External

- Regulatory agencies during audits
- Customers

MAIN DUTIES AND RESPONSIBILITIES

- Coordinate and manage the timely delivery of validation activities
- Review and approve validation documentation
- Line management of both permanent and contractor resources
- Ensure Validation procedures and activities are aligned with current GMP regulatory requirements

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 Higher Educational qualifications	☒	☐	
Knowledge and experience Experience as defined by type/level (not length)			
At least 5 years' experience of Validation within a Biopharma facility , including experience of Process, Cleaning, Capital Equipment systems, Autoclaves and sterile facilities	☒	☐	
Biologicals Pharma experience Sterile manufacturing	☐	☒	
Skills and capabilities			
Word, Excel experience Coordination and understanding of complex issues Ability to liaise at all business levels and communicate effectively to deliver service and documentation to a high standard.	☒	☐	
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

Job description agreed with the post holder:

Employee signature: …….. Date:……

Print name:…….....

Manager’s signature:…….. Date:……

Print name:…….....…