Job description

Job title	Process Equipment and Facility Team Leader
Directorate	PBL: Engineering : Validation
Pay band	Grade SEO / Level 2
Responsible to	Equipment Validation manager
Base/location	Porton Down Wiltshire
Hours/sessions per week	37.5
Job type	Permanent

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 Validation team comprises of approximately 30 specialists on a permanent or contractual basis. The scope of Validation activities for this role covers, General re-qualification of equipment, facilities and utilities with an experienced knowledge base of Computer System Validation, Cleaning validation, and the delivery of capital equipment into beneficial use.
This role of Process Equipment and Facility team leader reports into the Equipment Validation manager and is responsible for coordinating the execution of the Validation Master Plan with respect to the requalification of equipment, utilities and facilities.
A knowledge of Validation life cycle documentation deliverables and how to implement a Risk based approach is central to the skills base of this position

JOB SUMMARY

The purpose of the Process Equipment and Facility Team Leader role is to coordinate the execution of requalification activities in accordance with the VMP. In addition to provide technical expertise with respect to the scope of validation activities including utilities, Clean room qualification, sterile systems validation and the qualification of analytical laboratory systems.

Communication and key working relationships

<u>Internal</u>

- Managerial and technical staff to achieve agreed deadlines and manage expectations

- Engineering, Quality, Quality control, Site Safety and Security

External

- Regulatory auditors (Predominantly, MHRA and US FDA)
- Suppliers of services and systems
- Customers

MAIN DUTIES AND RESPONSIBILITIES

1. To coordinate the execution of the Validation Master Plan with respect to the requalification of equipment and facilities.
2. To assess resource requirements and manage direct reports, ensuring satisfactory coordination with stake-holders to guarantee timely delivery of systems into operational use
3. To review and approve validation documentation ensuring compliance to PBL policies and procedures.
4. Act as subject matter expert for the validation of sterility systems, facilities, and utilities
5. Assess Change control documentation to determine change impact with respect to the validation requirements and report appropriately.
6. To lead Equipment Validation discussions during audits
7. To support operational areas in the implementation of change
8. To ensure the timely completion of Deviations and the closure of CAPAs
9. To lead and manage direct reports developing their skills to meet the business need

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 in Science or Engineering or equivalent and recognised academic achievement	☒	☐	
Knowledge and experience Experience as defined by type/level (not length)			
At least 10 years validation experience ideally within a Biopharma environment	☒	☐	
Biotechnology experience	☐	☒	
Statistical evaluation of data	☐	☒	
Understanding of Validation Life Cycle	☒	☐	
Project management	☒	☐	
Skills and capabilities			
People line management	☒	☐	
Coordination of cross functional teams	☒	☐	
Management of internal customer expectations.	☒	☐	
Statistical package use	☐	☒	
Good computer sklls : Word, Excel,	☒	☐	
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:…….....…