Job description

Job title	Validation Manager
Division	Engineering
Career Level	2
Responsible to	Director of Engineering

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range development and manufacturing roles for biopharmaceuticals. This also includes all associated support functions from logistics through to engineering, quality control / quality assurance, regulatory affairs and management. The Company manufactures two licensed products, Erwinase® and the UK's Anthrax Vaccine as well as providing R&D services for product development.

[PLEASE ADD PARAGRAPH SPECIFIC TO DIRECTORATE OR DIVISION/DEPT]

JOB SUMMARY

The site Validation Manager has responsibility and accountability for ensuring that the facilities, equipment, systems and processes used in the manufacture and testing of the Sites products have been appropriately validated and maintained in a validated state.

Communication and key working relationships

Internal

- Senior Quality and Production Managers
- Project team leaders
- Validation technologists
- Project Managers
- Internal auditors
- External auditors (regulators or customers)

External

- Equipment suppliers

MAIN DUTIES AND RESPONSIBILITIES

- Responsible for driving all aspects of Validation Life Cycle
- Develop and maintain the Validation Master Plan ensuring it reflects current practices
- Define and optimise the overall validation strategies, policies, and programs. Strategic planning to include benchmarking against industry trends as well as continuous improvement in the validation program against current compliance standards and regulations.
- Manage the development and execution of validation protocols for all facility services, utilities, equipment, and systems including computer systems involved in regulatory processes. Manage the development and execution of the equipment cleaning validation program. Oversee the validation of laboratory equipment and method validation
- Manage the development and implementation of a validation maintenance program which periodically reviews the status of validated systems.
- Interface with appropriate regulatory inspectors on all validation issues, and present the validation program in regulatory audits.
- Manage the validation group. Support the development plan for validation activities. Set priorities for self and staff within the guidelines set by supervision. Responsible for determining the need for, identifying, contracting, and managing the efforts of outside consultants and contractors when necessary to maintain the facility validation program compliant with regulatory requirements
- Determine project resource requirements for engineering/ validation including capacity / capability. Where required assess, appoint, control and direct specific Contractors and Suppliers
- Responsible for QMS compliance of validation

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		
General education to Degree in a scientific/engineering discipline or equivalent	☒	☐
Minimum 5 years pharmaceutical industry experience	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
[Previous knowledge of Biopharma processes and/or Validation life cycle documentation	☒	☐
Experience leading and developing a Validation team	☒	☐
Skills and capabilities		
Track record of motivating people and managing teams	☒	☐
Experience of dealing with internal customers, identifying and taking the lead in delivering work programmes, reporting progress, dealing with issues to ensure customer satisfaction.	☐	☒
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:	