

Job description

Job title	Process Validation Lead
Division	Engineering
Career Level	2
Responsible to	Validation Manager

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.

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, Computer System Validation, Cleaning validation, Process validation and the delivery of capital equipment into beneficial use.

JOB SUMMARY

This role of the Process Validation Lead is to define and coordinate the execution of Performance Qualification and Process Performance Qualification activities in support of PBL manufacturing activities and in accordance with Regulatory requirements and to manage the Process Validation team at PBL.

The role will include the writing, review, approval (as required) and execution of process validation plans, protocols and reports and the coordination of support activities to deliver on time a high standard of documentation.

The position holder will be expected to attend Project group meetings, liaise with PBL support teams, regulatory bodies and peers to establish data for inclusion into protocols and reports,

The position holder should be prepared to execute and witness Process validation studies in line with the Production schedule.

Communication and key working relationships

Internal

- Managerial and technical staff to achieve agreed deadlines and manage expectations
- Engineering, Quality, Quality control, Site Safety and Security
- Validation Programme Manager

External

- Regulatory agencies during audits (Predominantly, MHRA and US FDA)
- Customers

MAIN DUTIES AND RESPONSIBILITIES

1. To coordinate the execution of the Validation Master Plan with respect to Process Validation activities.
2. Assess Change Control documentation to determine change impact with respect to the validation requirements and report appropriately.
3. To support operational areas in the implementation of change.
4. Supports Process Validation activities.
5. Define Process Validation Strategies.
6. Author and review Process Validation plans, protocols and reports ensuring compliance to PBL policies and procedures as required.
7. Approve Process Validation plans, protocols and reports ensuring compliance to PBL policies and procedures as required.
8. Schedule and support Process Validation executions.
9. High level of technical and scientific writing required.
10. Understand and apply statistical tools for development of protocols and data analysis for Process Validation (as per current FDA/MHRA Process validation lifecycle guidelines).
11. Lead Continued Process Verification activities including the generation of CPV plans and reporting.
12. Present Process Validation documents at regulatory audits.
13. Performs process investigations with relevant departments as required.
14. Performs product and process impact assessments.
15. Participates in or leads process and quality risk assessments.
16. Presents findings at group and at interdepartmental meetings.
17. Communicate information on current process data which may impact Process Validation.
18. Maintain and review the Product Control Strategy for all products. Understand the functional relationships that link CMA/ CPP/PP to CQA.
19. To ensure the timely completion of Deviations and the closure of CAPAs
20. Coordinate Contractor or permanent resources to deliver timely documentation in support of Process Validation activities.

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 (E²)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	<input checked="" type="checkbox"/>	
A good standard of written and spoken English Language	<input checked="" type="checkbox"/>	
Qualification		
Degree in Science or Engineering or equivalent and recognised academic achievement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Knowledge and experience Experience as defined by type/level (not length)		
At least 10 years validation experience ideally within a Biopharma environment	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Biotechnology experience	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Statistical evaluation of data	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Understanding of Validation Life Cycle	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Project management	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Skills and capabilities		
People line management	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coordination of cross functional teams	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Management of internal customer expectations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Statistical package use	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Good computer skills : Word, Excel,	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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	<input checked="" type="checkbox"/>	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	