Job description

Job title	Process Validation Specialist
Division	Engineering
Career Level	3
Responsible to	Process Validation Lead

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 with an experienced knowledge base of Computer System Validation, Cleaning Validation, Process Validation and the delivery of capital equipment into beneficial use.

JOB SUMMARY

This role is to coordinate the timely completion of Process Validation studies in support of PBL manufacturing activities and Regulatory requirements. The role will include the writing, review 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
- Process Validation Lead
- Validation 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.
7. Schedule and support Process Validation executions.
8. High level of technical and scientific writing required.
9. Understand and apply statistical tools for development of protocols and data analysis for Process Validation (as per current FDA/MHRA Process validation lifecycle guidelines).
10. Present Process Validation documents at regulatory audits.
11. Perform process investigations with relevant departments as required.
12. Perform product and process impact assessments.
13. Participate in or lead process and quality risk assessments.
14. Present findings at group and at interdepartmental meetings.
15. Communicate information on current process data which may impact Process Validation.
16. Maintain and review the Product Control Strategy for all products. Understand the functional relationships that link CMA/CPP to CQA.
17. To ensure the timely completion of Deviations and the closure of CAPAs.
18. Participate in Continued Process Verification Activities (CPV) including the generation of CPV plans and CPV reporting.

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 experience ideally within a Biopharma environment	☒	☐
Biotechnology experience	☐	☒
Statistical evaluation of data	☐	☒
Understanding of the 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 skills, 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	☒	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	