Job description

Job title	Process Validation Specialist
Directorate	PBL: Engineering : Validation
Pay band	Level 3
Responsible to	Process Validation Lead
Base/location	Porton Down Wiltshire
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd, Porton Down has approximately 350 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The company 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 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.
The purpose of the Process Validation Specialist role is to coordinate the execution of Performance Qualification and Process Performance Qualification activities as in accordance with Regulatory requirements.
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

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

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 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	✓		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:…….....…