Job description

Job title	Computer Systems Validation Manager
Directorate	Validation
Career Level	Level 2
Responsible to	Validation program manager
Base/location	Porton Down
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 activities within pharmaceutical production, process and analytical development, quality control and quality assurance. The business carries out the manufacture of Erwinase® and Anthrax Vaccine as well as contract manufacturing projects.

Computer Systems Validation Manager:

This role lies within the Validation team at PBL. The role is to lead and manage the site Computer Systems Validation program ensuring the site is compliant with respect to Regulatory requirements for CSV, Industry standards and PBL policies and procedures.

JOB SUMMARY

To lead the PBL site for compliance to CSV Regulatory and Industry standards. The job holder will be expected to drive policies, procedures and working practices which are compliant to MHRA and FDA Regulatory expectations and aligned with Industry (GAMP/ISPE) standards.

The job holder will be the Subject Matter Site Expert (SME) for CSV leading the validation team to deliver the business need. This will involve representation at regulatory Inspections, senior management meetings and to provide support for the content of the VMP.

Communication and key working relationships

<u>Internal</u>

- Senior Management
- Departmental team leaders

- Line management staff

External

- Regulatory authorities
- Customers
- External SMEs / consultants

MAIN DUTIES AND RESPONSIBILITIES

- Coordinate CSV activities to deliver timely completion of the VMP
- Ensure Policies and Procedures are compliant with Regulatory and Industry standards
- Lead the CSV team to deliver the business need
- Site SME on CSV.

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			
Higher educational (Degree or equivalent) qualification in Sciences	☒	☐	
Knowledge and experience Experience as defined by type/level (not length)			
Minimum 5 years experience with CSV in a GMP environment	☒	☐	
Data integrity understanding	☒	☐	
CFR 21 part 11 assessment experience	☒	☐	
Fundamentals of GAMP	☒	☐	
Skills and capabilities			
Microsoft Office: Word/ Excel;,PP	☒	☐	
Microsoft Project	☐	☒	
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:…….....…