Job description

Job Title	Computer Systems Validation Specialist
PBL Directorate	Engineering
Pay band	Career Level 2
Responsible to	Computer Systems Validation Manager
Base/location	Porton – Down Wiltshire
Hours/sessions per week	37.5 hrs
Job type	Permanent

INTRODUCTION

Porton Biopharma, Porton Down has approximately 300 staff, performing a range of process and analytical development, production, quality control and quality assurance roles associated with the development and manufacture of biopharmaceuticals.

The department carries out the manufacture of Erwinase and Anthrax Vaccine, as well as contract manufacturing projects.

JOB SUMMARY

This role within the Validation team is necessary to manage and execute validation activities associated with the cGMP compliance of computerised and software systems, ensuring that they are appropriately qualified and fit for operational use.

The role will ensure that the commercial risks associated with disaster recovery and data life cycle compatibility are addressed for each computer system guaranteeing long term availability of business critical systems and data.

This role is a hands-on position and requires the post holder to be able balance multiple project based activities, coordinating the generation, review and execution of validation protocols with the relevant stake-holders.

In addition this role will have an input into CAPEX projects for example the Freeze Dryer and the 3000L Fermenter where there is a significant computerised / software content, ensuring

that systems have been appropriately designed and qualified to ensure effective and cGMP compliant operational use.

To lead and execute CSV validation activities of computerised systems and associated equipment in accordance with current regulatory requirements.

To minimize business risk associated with the processing and storage of electronic documentation ensuring continuity over the equipment and product's life cycle.

Communication and key working relationships

Internal

- Validation CSV Manager
- Validation Project Team Leader
- Validation Technologists/ Technical Specialists
- Unit Managers,
- Operations
- Project Managers
- Quality
- Internal Auditors
- GMP Engineering

External

- Equipment Suppliers/ Vendors
- External Customers and Regulatory Auditors.

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 organization.

MAIN DUTIES AND RESPONSIBILITIES

1. Take the lead in computer system validation and compliance, manage and deliver specific Validation Projects according to the business priorities, including work scheduling and supervision of junior members of staff.
2. Comfortable working alone or within the matrix management system.
3. Continuous improvement of validation systems and procedures to ensure efficiency and best practice within the industry and to stay abreast of changing regulatory expectations.
4. Write, review and approve validation documentation including protocols and reports and manage the timely closure of any discrepancies or non-conformities.
5. Providing a reliable service to our internal customers to ensure that timescales are met and work is carried out to meet expectations.
6. Maintaining the ongoing compliant status of computer systems associated with equipment, facilities and utilities by involvement of the scheduling of activities.
7. Communicating validation activities with our internal and external customers and working with them to resolve problems and conflicts.

8. In line with overall responsibilities, perform additional tasks assigned by the line manager.
9. Undertake all work in accordance with Code of Safety Practice and site Quality Policies.

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			
General education to BTEC National Certificate or equivalent, including science.	A		
BSc in Engineering, Science or IT.		A	
Knowledge and experience Experience as defined by type/level (not length)			
Substantial experience of generation, execution and review of validation protocols, reports and technical documents.	A &I		
Experience of validation life cycle activities for computerised systems.	A &I		
Substantial practical experience of working within a GMP quality system.	A &I		
Experience of dealing with internal customers, identifying and delivering work programmes, reporting progress, dealing with issues to ensure	A &I		
Experience of supervising junior staff.	A &I		
Practical experience within a biopharmaceutical manufacturing environment.		A &I	
Experience of the validation of production processes.		A &I	
Scheduling experience.		A &I	
Practical experience dealing with internal and external, including regulatory agencies, inspectors and auditors.		A &I	
Experience of working at suppliers sites including outside UK.		A &I	

Skills and capabilities			
A thorough understanding of the equipment validation life cycle activities for pharmaceutical manufacture and testing equipment.	A &I		
A comprehensive understanding of EU and FDA regulatory requirements relating to validation including (but not limited to) UK/EU GMP Annex 11 and 21 CFR Part11.	A &I		
An understanding of GAMP processes.	A &I		
Technical understanding of computerised systems including PLCs, SCADA, networked systems, laboratory systems, databases, layered software as used in a GxP environment.	A &I		
Understanding of the implementation risk in a site wide validation approach.	A &I		
Understanding of techniques employed to qualify legacy systems.	A &I		
Interact with customers at all levels; able to communicate with customers in a professional manner and keep all parties updated as required.	A &I		
Critical assessment of reports and technical documents against customer and regulatory specifications and standards.	A &I		
Team Leadership and supervisory skills.	A &I		
Personal effectiveness.	A &I		
Proactive responsibility.	A &I		
Project orientation.	A &I		
Able to convey complex ideas and opinions clearly and concisely to a range of audiences.	A &I		

An understanding of GLP validation requirements.		A &I	
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:…….....…