Job description

Job title	Computer Systems Validation Specialist
Division	Engineering
Career Level	2
Responsible to	Computer Systems Validation Manager

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized company 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.

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 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

MAIN DUTIES AND RESPONSIBILITIES

- 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.
- Comfortable working alone or within the matrix management system.
- Continuous improvement of validation systems and procedures to ensure efficiency and best practice within the industry and to stay abreast of changing regulatory expectations.
- Write, review and approve validation documentation including protocols and reports and manage the timely closure of any discrepancies or non-conformities.
- Providing a reliable service to our internal customers to ensure that timescales are met and work is carried out to meet expectations.
- Maintaining the ongoing compliant status of computer systems associated with equipment, facilities and utilities by involvement of the scheduling of activities.
- Communicating validation activities with our internal and external customers and working with them to resolve problems and conflicts.
- In line with overall responsibilities, perform additional tasks assigned by the line manager.
- 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.

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		
General education to BTEC National Certificate or equivalent, including science.	☒	☐
BSc in Engineering, Science or IT	☐	☒
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.	☒	☐
Experience of validation life cycle activities for computerised systems.	☒	☐
Substantial practical experience of working within a GMP quality system.	☒	☐
Experience of working with product Serialisation qualification.	☐	☒
Experience of dealing with internal customers, identifying and delivering work programs, reporting progress and dealing with issues.	☒	☐
Practical experience within a biopharmaceutical manufacturing environment.	☐	☒
Practical experience dealing with internal and external audits, including regulatory agencies, inspectors and auditors.	☐	☒
Skills and capabilities		
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.	☒	☐
An understanding of GAMP processes.	☒	☐
Technical understanding of computerised systems including PLCs, SCADA, networked systems, laboratory systems, databases, layered software as used in a GxP environment.	☒	☐
Understanding of the implementation risk in a site wide validation approach.	☐	☒
Critical assessment of reports and technical documents against customer and regulatory specifications and standards.	☐	☒

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:	