

## Job description

<b>Job title</b>	Quality Assurance Administrator
<b>Directorate</b>	Quality
<b>Pay band</b>	5
<b>Responsible to</b>	Unit Manager – QA Documentation
<b>Base/location</b>	Porton
<b>Hours/sessions per week</b>	37.5
<b>Job type</b>	Permanent

### INTRODUCTION

Porton Biopharma Ltd, Porton Down has approximately 300 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The department carries out the manufacture of Erwinase and Anthrax Vaccine as well as contract manufacturing projects.

The Quality Assurance (QA) team works in a regulated GMP environment which manages the non-conformance and CAPA system, provides QA oversight of manufacturing and testing activities and performs investigations linked to manufacturing and testing activities.

The QA Admin team provide vital support to QA, administering a number of systems and providing an interface between PBL and QA to manage and control the receipt, tracking, review and distribution of documents.

### JOB SUMMARY

To administer and maintain the Change Management and Quality Risk Management databases. Maintain a document tracking system and provide general administrative support to the activities of the QA Compliance Team.

### Communication and key working relationships

#### Internal

- PBL Documentation and Archive Service Customers.
- MasterControl EQMS System users.
- Production, Quality, Safety, Validation, Contractors, Facilities Management, Engineering and Research.

#### External

- Regulatory Inspectors, Commercial Customers, Consultants, Suppliers

## **MAIN DUTIES AND RESPONSIBILITIES**

- To manage and maintain the non-conformance, change management and risk management databases.
- To maintain a document tracking system for QA to manage the incoming, distribution, review and return of documents within QA.
- To liaise with QA and internal customers to ensure that documents are processed effectively and efficiently.
- Review Change Management and Quality Risk Management documentation and make decisions as guided by the relevant SOP's.
- To organise and prepare for the Change Control escalation and Change request review board meetings and co-ordinate and minute the meetings.
- To design and produce reports relating to appropriate databases and activities.
- To supervise/assist new and temporary staff, on a limited basis.
- To frequently use computerised systems including inputting data that requires a high degree of accuracy.
- To input archive data onto the database and prepare records for archive storage.
- To support the introduction of an electronic quality management system.
- To photocopy / scan and word process documents, letters, emails and reports when required.
- To provide general office administrative support to the QA teams, e.g. Filing, photocopying, ordering consumables/stationery, stock control, arranging meetings.
- Undertake work in accordance with Health and Safety policies and procedures.
- To work within the bounds of applicable Quality Systems.
- To comply with PBL Policies and Procedures.

### **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
<b>Qualification</b>			
5 GCSEs or equivalent including English and a scientific subject	✓		A/I
Educated to NVQ 2 level in a relevant subject or equivalent level of qualification or significant equivalent previous proven experience.		✓	A/I
<b>Knowledge and experience</b>			
Experience as defined by type/level (not length)			
Previous experience of working in an administrative environment using computerised data systems.	✓		A/I
Experience of working in a health care environment.		✓	A/I
Awareness of a range of Health Services provisions.		✓	A/I
Working knowledge of Microsoft Office including Word and Excel.		✓	A/I
Understanding of Data Protection legislation.		✓	A/I
<b>Skills and capabilities</b>			
Clear communicator with good writing, data entry and telephone skills ensuring accuracy.	✓		A/I
Ability to work effectively as part of a team.	✓		A/I
Problem solving skills.	✓		
Able to work on own initiative, organising and prioritising own workload to set deadlines.	✓		A/I
An ability to maintain confidentiality and trust.	✓		A/I
Good time keeping.	✓		A/I
Flexible approach to work.	✓		A/I
<b>Equality and diversity</b>			
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
<b>*Assessment will take place with reference to the following information</b>			
<b>A = Application form</b>	<b>I = Interview</b>	<b>C = Certificate</b>	<b>T = Test</b>

Job description agreed with the post holder:

Employee signature: ..... Date:.....

Print name:.....

Manager's signature:..... Date:.....

Print name:.....