Job description

Job title	QMS Documentation Controller and GxP Archivist
Division	Quality
Career Level	5
Responsible to	QA Document Control Leader

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range of development and manufacturing roles for biopharmaceuticals. This also includes all associated support functions from logistics through to engineering, quality control / quality assurance, regulatory affairs and management. The Company manufactures two licensed products, Erwinase® and the UK's Anthrax Vaccine as well as providing R&D services for product development.

Quality Assurance – Documentation

Unambiguous, clear documentation is an essential part of the Quality Management System. It prevents, for example, errors from spoken communication, provides clear instructions and therefore ensures the quality and integrity of the work performed and the resulting data with resultant records providing a history of the work performed. To support this, staff within QA Documentation provide a variety of Document Control functions / services which include the document creation, formatting, scanning and controlled distribution of PBL documents.
In addition; the department is also responsible for managing the sites Change Control system (managing the review process for critical changes made), the Quality Risk Assessment system (reviewing and mitigating risks to product) and managing the provision of the Archive Service. (long term retention of documents and records).

Quality Assurance – Archive Service

Document Control includes the requirement for long term retention of 'Documents' ('Records' and 'Instructions'). Documents are catalogued and stored within purpose built Archive Facilities, which are monitored and maintained to prevent degradation of the Documents. Document interactions (retrieval, provision of copies, disposal etc.) are overseen and managed by the Archive Service.

JOB SUMMARY

- To control the input and subsequent tracking of documents (including identification, filing, return and disposal of records) using an appropriate tracking system
- To assist in the management, distribution and control of Quality Documentation
- To prepare documents for addition to the archive catalogue
- To perform critical Data entries correctly and with a high degree of accuracy
- Provide First Line Support with completion of QMS processes, answering end user (customer) queries and resolving problems
- To provide training to other staff (including new starters and service end users)

- General office and administrative duties to support the activities of the QMS Administration Group (scanning, room bookings, etc.)

Communication and key working relationships

Internal

- Document Control personnel
- PBL Document Control Customers
- MasterControl EQMS System users
- The site IT services provider.
- The Site Primary Maintenance Contractor (e.g. Emcor)
- Site Security personnel

External

Regulatory Inspectors

- Commercial Customers
- Consultants (e.g. MasterControl Technical Support and off-site Archive storage facilities)
- Suppliers

MAIN DUTIES AND RESPONSIBILITIES

- To manage and maintain the necessary tracking system(s) / database(s)
- To liaise with internal customers to ensure:
    - Efficient and effective processing of Quality Documentation
    - Resolution of customer queries
- Make decisions on processing Quality Documentation based on content and as guided by SOPs
- Perform the preparation of records for storage
- Use computerised systems including inputting multiple critical data entries which require a high degree of accuracy
- Provision of first line support, via email, telephone or face-to-face, with service users to ensure compliance with defined processes and effective processing
- Provision of training both to individuals and groups, including the generation and assessment of training materials
- To provide general office administrative support to the team, e.g. Filing, photocopying, stock control, arranging meetings, room bookings, car hire etc.

General:

- 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.

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		
5 GCSEs or equivalent, including English, Maths and a Scientific subject.	☒	☐
Educated to NVQ 2 level in a relevant subject or equivalent level of qualification or significant equivalent previous proven experience.	☐	☒
RSA 3 in Typing, work processing or a European Computer Driving License (ECDL) or equivalent	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Previous experience of working in an administrative environment using computerised data systems, document control or archive experience.	☒	☐
Working knowledge of Microsoft Office, including Word and Excel.	☒	☐
Experience of working in a health care or pharmaceutical environment.	☐	☒
Understanding of Data Protection legislation.	☐	☒
Skills and capabilities		
Clear communicator with good writing, data entry and telephone skills ensuring accuracy.	☒	☐
Ability to work effectively as part of a team.	☒	☐
Problem solving skills.	☒	☐
Able to work on own initiative, organizing and prioritizing own workload to set deadlines.	☒	☐
An ability to maintain confidentiality and trust.	☒	☐
Good time keeping.	☒	☐
Flexible approach to work.	☒	☐
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: Jacqueline Needham	Date:
Manager Signature:	