Job description

Job title	Quality Systems Manager
Directorate	Quality
Career Level	2
Responsible to	QMS & Compliance Manager
Base/location	Porton
Hours/sessions per week	37.5
Job type	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.

JOB SUMMARY

Provide leadership and QA management for: QA Documentation, GxP Training, Change Control and Quality Risk Assessment processes. To monitor all aspects of Quality System performance.

Provide leadership, communication and expertise in running the quality system in Microbiology Services, Development & Production.

Communication and key working relationships

Internal

- Senior Quality Managers and other Senior Managers
- PBL staff across all levels of PBL

External

- National and international collaborations and customers
- External customers
- Regulatory Authorities

MAIN DUTIES AND RESPONSIBILITIES

- To lead, motivate and manage multidisciplinary teams with the responsibility for delivery and maintenance of training, document control, change control and risk management processes.
- To monitor the performance of all Quality System metrics, to lead on identification of trends and to advise Senior Management of outcomes.
- Ensure the training system meets the needs of the business and quality system and regulatory requirements.
- Ensure specified elements of the Quality System meet the business need and regulatory requirements.
- Monitor and report on agreed KPI's for the quality system and identify and implement improvements to the reports as appropriate.
- Lead the development and implementation of an ongoing Quality Improvement plan to maximise efficiency of the Quality System process.
- Using Quality System expertise and knowledge to contribute to the strategy and vision of PBL.
- Operational delivery of specific project outcomes in accordance with strategic business objectives.
- Manage assigned budget within authority level (£10,000)
- Comply with PBL Policies
- In line with overall responsibilities, perform additional tasks assigned by the line manager.

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			
Educated to degree level in life science or chemistry or equivalent level qualification or significant experience of working at a similar level in a relevant specialist area	☒	☐	A/I
Post-graduate degree in a life/applied science or equivalent	☐	☒	A/I
Knowledge and experience Experience as defined by type/level (not length)			
Significant experience of management of multidisciplinary teams delivering a variety of services & projects	☒	☐	A/I
Experience of generation, analysis, management & control of GxP documentation, data and records	☒	☐	A/I
Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction	☒	☐	A/I
Substantial practical experience of Quality Assurance within a GxP environment	☒	☐	A/I
Practical experience within a biopharmaceutical manufacturing environment	☒	☐	A/I
Experience of auditing manufacturing processes and systems within a GMP environment	☐	☒	A/I
Skills and capabilities			
Must be able to provide and receive highly complex, sensitive or contentious information, negotiate with senior stakeholders on difficult and controversial issues, and present complex and sensitive information to large and influential groups	☒	☐	A/I
Problem solving skills and ability to respond to sudden unexpected demands	☒	☐	A/I
Strategic thinking – ability to anticipate and resolve problems before they arise	☒	☐	A/I
Demonstrated capability to plan over short, medium and long-term timeframes and adjust plans and resource requirements accordingly	☒	☐	A/I
Must be able to prioritize own work effectively and be able to direct activities of others. Experience of managing and motivating a team and reviewing performance of the individuals.	☒	☐	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:…….....…