Job description

Job title	Product Quality Manager
Directorate	Quality
Career Level	2
Responsible to	QMS and Compliance Lead
Base/location	Porton
Hours/sessions per week	37.5
Job type	Fixed Term 18-month

INTRODUCTION

Porton Biopharma Ltd, Porton Down has approximately 400 staff, 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.

JOB SUMMARY

To provide leadership and QA management for the operation of batch review/release, nonconformance, change control and product risk assessment systems.

To monitor performance of the systems.

To provide leadership, communication and expertise to continuously improve QA compliance across PBL

Communication and key working relationships

Internal

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

External

- National and International customers and suppliers
- Regulatory Inspectors

MAIN DUTIES AND RESPONSIBILITIES

1. Lead, motivate and manage multidisciplinary teams with assigned responsibility for delivery and maintenance of services related to batch review, non-conformance Management, change control management, Quality Risk management and project delivery.
2. Ensure the batch review release system is effective in the timely release of in process and finished pharmaceutical products.
3. Where applicable, fulfil legal duties of the QP as defined in Annex 16 of the European Union Guide to GMP
4. Ensure the non-conformance management system meets regulatory requirements and industry expectations.
5. Ensure the operation of the change control system supports the effective changes to improve systems and processes.
6. Ensure the Quality Risk Management system supports product impact assessments.
7. Provide Quality advice related to compliance and QA operational issues.
8. Review and approve QA and validation documents (e.g. SOPs, protocols, reports)
9. Monitor the performance of the systems under area of responsibility using KPIs and report to management.
10. Develop and implement an ongoing Quality Improvement Plan related to the systems under area of responsibility
11. Manage assigned budget within authority level
12. 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
Eligibility			
Right to work in the UK	☒	☐	
A good standard of written and spoken English Language	☒	☐	
Qualification			
Educated to degree level in life science or chemistry or equivalent Qualification/Experience	☒	☐	A/I
Post-graduate degree in life /applied science or equivalent	☐	☒	A/I
Eligibility to act as a QP under the provisions of Directive 2011/83/EC	☐	☒	
Knowledge and experience Experience as defined by type/level (not length)			
Significant experience of managing multidisciplinary teams offering a variety of services and projects	☒	☐	A/I
Experience of operating and managing quality systems for compliance to regulatory requirements (e.g. batch release, non-conformance, risk management) and a focus on continuous improvement.	☒	☐	A/I
Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction	☒	☐	
Substantial practical experience within a GMP environment, particularly in the context of biologics and steriles manufacture.	☒	☐	
Must have operational knowledge of EU/US pharmaceutical regulatory requirements, particularly for biologics and sterile products.	☒	☐	
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
Must have problem solving skills and the capability to respond to sudden unexpected demands	☒	☐	A/I
Must be capable of identifying potential product	☒	☐	

impact from the analysis of adverse events.			
Must have the capacity to obtain process and product knowledge required to provide advice to Operational teams and to respond to adverse events	☒	☐	
Must be able to prioritise own work and direct activities of others effectively. Experience of /EC/ECmanaging and motivating a team and reviewing the performance of individuals	☒	☐	
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:…….....…