Job description

Job title	QMS and Compliance Lead
Division	Quality
Career Level	1
Responsible to	Director of Quality

INTRODUCTION

Porton Biopharma Ltd, based in 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.

JOB SUMMARY

Reporting to the Director of Quality, the QMS and Compliance Lead will assist in the delivery of autonomous and innovative leadership to achieve:

- Delivery of compliant Quality Systems, and development of a world-class QMS, through effective leadership of the QMS and Compliance teams;
- Effective and swift development of health interventions, and increase the Company's competitive edge in translational research;
- Delivery of a leading, discrete, and complex business, to meet the needs of the Company's ongoing future strategy;
- Further enhancement of the Company's good reputation with all relevant stakeholders and sectors;
- Reduction in regulatory obstacles through application of new technologies and an effective and motivated workforce;
- Improvement of current levels of grant and other income;
- Delivery of the strategic direction, and business objectives, of the Company;
- Taking full responsibility of Quality Systems (including GxP).

Communication and key working relationships

Internal

- Scientific and management of colleagues throughout Porton Biopharma Ltd.

External

- National and international scientific experts, academic institutions, private and public sector customers.

MAIN DUTIES AND RESPONSIBILITIES

- Lead the QMS & Compliance teams to deliver compliant Quality systems, and develop a world-class QMS;
- Provide operational direction and leadership to a large team of GMP Quality professionals, Documentation control, & Archivist staff;
- Develop and manage the QA, GMP, & QMS programmes, policies, standards, and procedures to ensure conformance to the highest standards and regulatory agency requirements (MHRA, EU, FDA etc.);
- Establish processes and systems that support collaboration, compliance and are simple and effective;
- Lead and support where required with regulatory inspections;
- Further develop, implement and manage processes that align with, and drive, effective systems for change control, deviations and investigations, complaints, recalls, risk management and CAPA;
- Oversee GMP Quality system performance metrics, analyse compliance data and coordinate the necessary Quality reporting and escalation responses;
- Manage the processes for the Quality Management Review Board, Change Control Review Board and Risk Management forums;
- Provide expertise and guidance to senior management in the interpretation of global GMP regulations, ICH guidelines and internal policies and procedures;
- Promote continuous improvements in quality systems and department infrastructure; assist with creation/revision of appropriate SOPs, Code of Practices, Policies & Key Quality documents;
- Train, manage, and mentor QMS, GMP, & QA staff for the effective performance in PBL cGMP processes & compliance activities.

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		
MBA or equivalent senior management experience	☐	☒
Knowledge and experience		
Practical understanding and working knowledge of GMP regulations and Compliance requirements, with the ability to provide applicable guidance	☒	☐
Extensive experience in the pharmaceutical or biotech industry with extensive GMP QA experience within the FDA and/or EMA regulated environment	☒	☐
Proven experience of GMP QA management of a team of QA professionals	☒	☐
Comprehensive working knowledge of local, state, federal and international cGMP regulations; FDA/EU/ICH guidelines; validation standards, QMS and quality risk management principles	☒	☐
Proven experience with leading and hosting successful regulatory agency inspections	☒	☐
Skills and capabilities		
Programme and project management Service delivery and improvement Communication and stakeholder relations; Excellent verbal and written communication skills; Ability to effectively collaborate in a dynamic environment; Self-motivated and able to prioritize projects in a fast-paced environment; Ability to influence and motivate others towards compliance at all levels;	☒	☐

Strong communication skills with ability to work with cross-functional team members; Ability to resolve complex problems where analysis of situations or data requires an in-depth evaluation of various factors; Superb attention to detail, excellent review skills and the ability to organize and manage multiple tasks in a fast-paced environment; Exercise sound and balanced judgment in ensuring that written procedures are followed and in evaluating quality systems, processes, procedures, plans and protocols for compliance; Strong leadership experience and mentoring skills; Strong global knowledge and understanding of international regulations applicable to cGMP		
Corporate awareness; Leadership qualities including strategic influencing, political astuteness, inspiring change, drive for results, collaborative working, and personal improvement	☒	☐
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:	