Job description

Job title	Qualified Person
Division	Quality
Career Level	1
Responsible to	Lead QP

INTRODUCTION

Porton Biopharma Ltd, 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.

The position is part of the QP group of the Quality Assurance (QA) unit. The QP group acts independently to the rest of the QA unit and ensures best practices are used across the site for the manufacture of Quality, safe and efficacious products.

JOB SUMMARY

Accountable to the Lead QP for assisting in the delivery of autonomous and innovative Quality management to achieve:

- Release of safe and efficacious products manufactured to the required quality standard
- The enhancement of PBL's reputation with the private sector and others
- A reduction in regulatory hurdles in the application of new technologies
- A well-trained workforce
- The delivery of the strategic direction and business objectives of PBL "business", eg quality
- The targets and objectives agreed with line management
- Oversight and development for Quality Systems

Communication and key working relationships

Internal

- Scientific and management staff throughout PBL

External

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

MAIN DUTIES AND RESPONSIBILITIES
Assisting the Lead QP:

- To review batch manufacturing documentation to ensure compliance with EU GMP and the Product Specification File/marketing authorisation (or other where relevant)
- To certify Medicinal products for use in the EU and outside the EU (where relevant)
- To undertake audits in EU and third countries to ensure that sponsor manufacturing sites are operating in general compliance with EU GMP
- To provide advice and guidance to PBL staff and customers regarding pharma regulations.
- To provide technical and quality input to PBL projects related to products, facilities and equipment.
- To keep up to date with the requirements of the Medicines Authorities across the EU and rest of the world (where relevant).
- To review company project files (PSFs, commercial project files etc) to ensure compliance with the current regulatory requirements and PBL procedures.
- To provide input and assistance with relevant elements of the Quality management System (QMS) within the business.
- To provide assistance with regulatory inspections and client audits.
- To promote and uphold the highest standards of professionalism in order to create, maintain and enhance the reputation of the business amongst its customers and stakeholders both nationally and internationally.
- To deliver continuous improvement in all areas of the business to enhance the quality, delivery, rate of growth and competitiveness.
- To liaise and interact positively with appropriate regulatory authorities to ensure PBL compliance.

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		
Eligible QP as per directive 2001/83/EU	☒	☐
Knowledge and experience Experience as defined by type/level (not length)		
Extensive QA experience within the medicinal products/pharmaceutical industry	☒	☐
Experience in sterile manufacture	☐	☒
Experience in biopharmaceuticals	☐	☒
Skills and capabilities		
Programme and project management	☒	☐
Service delivery and improvement	☒	☐
Communication and stakeholder relations	☒	☐
Willingness to undergo security checks as appropriate	☒	☐
Willingness to travel and represent the business oversees	☒	☐
Corporate awareness	☒	☐
Leadership qualities including 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:	