Job description

Job title	Senior QA Specialist
Directorate	Quality
Career Level	2
Responsible to	Lead Qualified Person
Base/location	Porton Down
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd (PBL), Porton Down has approximately 350 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.

The QA department provides oversight, support, training and coaching to ensure the compliant manufacture, testing and supporting activities associated with the manufacture of medicinal products.

JOB SUMMARY

Accountable to the Lead Qualified Person (QP) to support the delivery of autonomous and innovative Quality management to achieve:

- release of safe and efficacious products produced to the required Quality standard
- a well trained workforce,
- developing the understanding of Quality throughout the organisation;
- the delivery of the strategic direction and business objectives of PBL" business", e.g. Quality
- the targets and objectives agreed with line management
- Oversight and development for Quality Systems

Communication and key working relationships

Internal

- Scientific and technical staff throughout PBL

External

- Suppliers, scientific experts, regulatory inspectors

MAIN DUTIES AND RESPONSIBILITIES

Assisting the Lead QP:

- To coach and mentor to improve problem solving and early problem resolution.
- To execute the review of deviations to assure the highest standards of compliance.
- To contribute to the Sterility Assurance Program through sharing of knowledge and experience.
- To review and approve documents within the QMS.
- To provide advice and guidance to PBL staff and Customers regarding pharmaceutical regulations.
- To provide Technical and Quality input to PBL projects related to products, facilities and equipment.
- To support the timely review of all Batch Manufacturing Documents to ensure compliance with EU GMP and the Product Specification File/marketing authorisation (or other where relevant).
- To undertake audits within the EU and other countries to ensure that sponsor manufacturing sites are operating in general compliance with EU GMP.
- To keep up to date with the requirements of the pharmaceutical regulations and across the EU and rest of world (where relevant).
- To provide input and assistance with development of relevant elements of the Quality Management System (QMS) within the business.
- To assist 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, Division and PBL 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.
- Willingness to travel and represent the business overseas.

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			
Current, valid Right to Work in the UK	☒	☐	A/I
Good standard of spoken and written English Language	☒	☐	A/I
Qualification			
Degree in life science or equivalent qualification	☒	☐	A/C
Knowledge and experience Experience as defined by type/level (not length)			
Extensive QA experience within the medicinal products/ pharmaceutical industry.	☒	☐	A/I
Experience in Sterile manufacture	☒	☐	A/I
Experience in Biopharmaceuticals	☐	☒	A/I
Skills and capabilities			
Programme and Project Management	☒	☐	A/I
Service delivery and improvement	☒	☐	A/I
Communication and stakeholder relations	☒	☐	A/I
Corporate awareness	☒	☐	A/I
Leadership qualities including inspiring change, drive for results, collaborative working and personal improvement	☒	☐	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:…….....