Job description

Job title	Quality Management System (QMS) Assistant / Development Scientist
Division	Development
Career Level	4
Responsible to	Senior Analytical Scientist / Quality Management System (QMS) Coordinator

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 Development Group undertakes development and technology transfer activities and plays a key role in the translational research activities of PBL. Its role is to develop manufacturing processes and associated analytical methods for use in the cGMP production of biotherapeutics and healthcare interventions. The group is organised into 4 core teams responsible for new product development, *in vitro* culture processes, downstream processes and analytical method development.

JOB SUMMARY

The successful applicant will play a key role supporting the management, maintenance and continuous improvement of ISO9001:2015 Quality Management System within the Development Group. This will include the management of the discrepancy and the internal audit system, conducting internal audits, document control, writing and reviewing quality documents, document training and recording of competence and ensuring ongoing compliance with ISO9001:2015 and other industrial regulations. The candidate will also be expected to maintain up-to-date knowledge of ISO, ICH guidelines, Federal Codes and other regulatory guidance relating to analytical methods and therefore awareness of the requirements of European and US cGMPs is highly desirable.

In addition, the post holder may also be required to perform routine testing of samples, to established methods, provided by other groups within PBL. Tasks will include the operation of HPLC and UPLC systems utilising a variety of separation chemistries for protein analysis as well as the use of a range of other biochemical methods for protein analysis such as enzyme activity assays, UV/Vis spectroscopy and gel electrophoresis.

Communication and key working relationships

Internal

- Line Manager
- Other functional heads and line managers within the Development Group
- Co-workers and project teams within the Development Group
- Staff in other departments, especially Quality, Manufacturing, Safety and Regulatory

External

- Laboratory supplier representatives and engineers
- Sub-contracted laboratories
- Regulatory Authorities and Inspectors

MAIN DUTIES AND RESPONSIBILITIES

- Support the management, maintenance, reporting and continuous improvement of the ISO9001:2015 Quality Management System.
- Ensure ongoing compliance with ISO9001:2015.
- Draft quality policies and procedures as required.
- Support the document control system.
- Coordinate and document internal audits, actions and completion of actions.
- Coordinate, support to ensure timely closure of actions raised from internal, external and regulatory auditors; facilitate closure of investigations arising from study discrepancies, customer feedback or other required improvements.
- Conduct internal audits as scheduled reporting and closing actions in a timely manner
- Review and identify areas of improvement within the quality system.
- Maintain awareness of Industry and International Regulatory Standards and guidance and implement where appropriate.
- Ensuring that work is undertaken in accordance with Porton Biopharma's Code of Safety Practice and relevant quality standards.
- Employ established analytical methods for the routine analysis of biopharmaceutical materials.
- Take responsibility for the preparation and documentation of reagents and for ensuring that consumables are available.
- Fully document all analytical testing in worksheets associated with standard protocols or in laboratory notebooks.
- Where necessary, help to adapt and apply analytical methods to analyse novel materials or assist in the development and implementation of new analytical methods.
- Write reports as required and assist with the preparation of experimental plans and protocols.
- Establish links and collaborations within PBL as necessary to benefit the project and/or department.
- Assist senior colleagues through understanding project priorities and prioritisation of own work.
- Complying with all Porton Biopharma policies and procedures
- To undertake all work in accordance with PBL wide and local quality systems, ensuring that data generated are accurate, valid and fit for purpose.
- Deputise, when required, for the Line Manager.
- Perform any other duties required by the Line Manager commensurate with the grade.

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		
Degree in Biological Science, Chemistry or similar	☒	☐
Knowledge and experience Experience as defined by type/level (not length)		
Experience of working to the requirements of a quality system such as ISO9001 or GMP	☒	☐
Experience in the implementation or maintenance of a Quality Management system	☐	☒
Experience in writing and complying to quality policies and procedures.	☒	☐
General laboratory experience including preparation of reagents	☒	☐
Knowledge and understanding of a range of techniques for the analysis of proteins and enzymes	☐	☒
Good understanding and experience of safe working laboratory practices	☒	☐
Skills and capabilities		
Ability to prioritise and plan own work	☒	☐
Good written and verbal communication skills	☒	☐
Proficiency in MS Office and other relevant software	☒	☐
Good organisational skills, meticulous and able to meet deadlines.	☒	☐
Problem solving / troubleshooting skills	☐	☒
Able to work to tight deadlines and under pressure	☒	☐
Self-motivating, proactive and flexible	☒	☐
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:	