Job description

Job title	Senior Analytical Scientist/Quality Management System (QMS) Coordinator
Directorate	Development - Analytical
Career Level	Level 4
Responsible to	Alka Bishop
Base/location	Porton Main Site/ Porton Science Park
Hours/sessions per week	37.5 hours
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd, 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 department 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; and develop products for early stage clinical evaluation. 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 candidate will develop analytical methods that will be used to characterise current manufacturing practices and influence process improvements as well as to support the introduction of new processes. They may also support routine sample testing provided by other groups within PBL.

The post holder will be involved in supporting the implementation, management, maintenance and continuous improvement of ISO9001:2015 Quality Management System. This will include coordinating and documenting the internal audit system, reviewing QMS efficiency, writing quality documents 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.

The applicant must be educated to at least degree level in a relevant subject. Have experience of implementing quality processes, continues improvement and working within a regulated environment. He or she must also have hands-on experience of developing, optimising, validating and implementing protein analysis methods, ideally in a biopharmaceutical setting. Familiarity with a broad range of protein sample preparation and analytical methods is required. Examples of relevant techniques are: immunoassays; 1D and 2D-gel electrophoresis; enzyme activity assays; HPLC, UPLC and UV/VIS spectroscopy and sample concentration methods. Experience of preparing technical documentation such as standard operating procedures, protocols and reports is required. Ability to come up with novel and innovative ideas is also desirable.

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.

Communication and key working relationships

Internal

- Line Manager
- Other functional heads, project teams and co-workers within the Development group
- Staff in other departments, especially Safety, QC, QA and Regulatory

External

- Academic researchers
- Industry contacts
- Suppliers and Engineers
- Sub-contracting laboratories
- Regulatory Authorities and Inspectors

MAIN DUTIES AND RESPONSIBILITIES

- Support the implementation, management, maintenance, reporting and continuous improvement of the ISO9001:2015 Quality Management System.
- Review the implementation and efficiency of the quality and inspection systems.
- Coordinate and document internal audits, actions and completion of actions.
- Draft quality policies and procedures as required.
- Review and identify areas of improvement within the quality system.
- Support the document control system.
- 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.
- Ensure ongoing compliance with ISO9001:2015.
- Maintain awareness of Industry and International Regulatory Standards and guidance and implement where appropriate.
- To identify, evaluate, adapt and introduce new analytical technologies where appropriate, providing sound scientific study to ensure such technologies are fit for purpose and cost effective.
- To contribute or take the lead on publications in national and international journals.
- Utilising established analytical methods as well as process and procedures for the analysis of biopharmaceutical materials.
- Where necessary adapting and applying analytical methods to analyse novel materials.
- Leading the development of methods for the analysis of biopharmaceuticals from feasibility, through method development and validation, to routine use within the Development group and/or transfer to QC.

- Establishing links and collaborations within and outside Porton Biopharma as necessary to benefit the project and/or department.
- Writing protocols, reports and study plans as required.
- Assisting senior colleagues in developing scientific and technical strategies.
- Taking responsibility for the supervision and training of junior staff where appropriate.
- Ensuring that work is undertaken in accordance with Porton Biopharma's Code of Safety Practice and relevant quality standards.
- 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.

Person specification

Description	Essential	Desirable	Assessment
Qualification			
Degree in Biological Science, Chemistry or similar	☒	☐	A, C
MSc or PhD in Biological Science, Chemistry or similar	☐	☒	A, C
Relevant Quality Management System Qualification	☐	☒	A, C
Knowledge and experience Experience as defined by type/level (not length)			
Experience in working within a regulated quality system particularly ISO 9001. Experience of maintaining quality management system. Experience in writing and complying to quality policies and procedures. Experience of working to tight deadlines to ensure timely closure of all types of actions. Experience in managing multiple projects. Experience and knowledge in the development of a range of analytical methods used for the analysis of biopharmaceutical products. Experience of advanced biochemical techniques. Experience of preparing technical documents such as proposals, protocols and reports. Ability to evaluate risks and build safe working procedures. Experience and knowledge of analytical method evaluation and technical transfer procedures.	☒	☐	A, I
Knowledge of regulatory guidance and requirements for biopharmaceuticals. Experience of interacting with Regulators. Presentation of work to internal customers. Experience of conducting and managing internal audits.	☐	☒	A, I
Skills and capabilities			
Good leadership skills. Good communication skills. Problem solving and troubleshooting skills Experience in planning and prioritising. Good organisational skills, meticulous and able to meet deadlines. Attention to detail. Teamwork. Self-motivating, proactive and flexible.	☒	☐	A, I

Eligibility			
Right to work in the UK	☒	☐	A, I
Fluent in English	☒	☐	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:…….....…