Job description

Job title	Senior Analytical Scientist
Division	Development
Career Level	Level 4
Responsible to	Method Development Lead

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range of development and manufacturing roles for biopharmaceuticals. This also includes all associated support functions from logistics through to engineering, quality control / quality assurance, regulatory affairs and management. The Company manufactures two licensed products, Erwinase® and the UK Anthrax Vaccine as well as providing R&D services for product development.

The Development Group undertakes continuous improvement and technology transfer activities and plays a key role in the translational research activities of PBL. The role of the group is to develop improved manufacturing processes and 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 fermentation processes, downstream processes and analytical method development.

JOB SUMMARY

Within the Development Group, the Analytical team is responsible for developing and performing analytical methods to support the manufacture of biopharmaceutical products. The methods are used to characterise existing manufacturing processes, to guide process improvements and to support the introduction of new processes.

The role of Senior Analytical Scientist in the Analytical Development team involves developing, optimising, qualifying and implementing analytical methods in a biopharmaceutical setting. The post holder will also be required to test samples provided by other groups within PBL by routine methods or by adaptation of existing methods, and to review data generated by colleagues within the team. Familiarity with a broad range of protein sample preparation and analytical methods is required. Examples of relevant techniques are chromatography (HPLC and UPLC); immunoassays; 1D and 2D-gel electrophoresis; UV/VIS spectroscopy; enzyme activity assays; and sample concentration methods.

Responsibilities include preparing technical documentation such as standard operating procedures, protocols and reports; maintaining 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.

Porton Biopharma Ltd promotes diversity in the workplace and is an equal opportunities employer.

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, including Quality, QC, Manufacturing, Safety and Regulatory Affairs.

External

- Academic researchers
- Industry contacts
- Laboratory supplier representatives and engineers
- Sub-contracted laboratories

MAIN DUTIES AND RESPONSIBILITIES

- Utilising established analytical methods 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.
- Taking ownership of projects ensuring appropriate methods, assays, techniques and systems are implemented and utilised to meet project targets.
- Being responsible for the provision, preparation and documentation of reagents and consumables required for testing samples or for projects and for documented storage of materials generated.
- Support routine testing as required.
- Assisting in identifying, evaluating and adapting new technologies where appropriate and helping to ensure that projects operate to a high scientific standard.
- Establishing links and collaborations within and outside Porton Biopharma as necessary to benefit the project and/or department.
- Fully documenting all analytical testing in worksheets associated with standard protocols or in the electronic laboratory notebook (ELN).
- 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.
- To review and check data to ensure accuracy and compliance to processes and procedures within set deadlines.
- Assisting senior colleagues by understanding project priorities and prioritising own work.
- Identifying new opportunities as they arise.
- Performing any other duties required by the Line Manager commensurate with grade.
- Ensuring that work is undertaken in accordance with Porton Biopharma's Code of Safety Practice and relevant quality standards.
- Maintaining awareness of Industry and International Regulatory Standards and guidance and implementing where appropriate.
- Complying with all Porton Biopharma policies and procedures.

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 Biochemistry or similar subject area	☒	☐
Knowledge and experience Experience as defined by type/level (not length)		
Good understanding and experience of safe working laboratory practices.	☒	☐
Experience of preparing technical documentation (SOPs, protocols, reports)	☒	☐
Hands-on experience of developing, optimising, qualifying or validating, and/or implementing analytical methods for pharmaceutical products.	☒	☐
Knowledge and understanding of a broad range of techniques used for the preparation and analysis of biopharmaceutical products (proteins and excipients).	☒	☐
Experience of using HPLC/UPLC systems	☒	☐
Experience of using Waters Empower software for analytical chromatography	☐	☒
Experience of performing spectrophotometric assays (including bioassays or immunoassays)	☐	☒
Experience of performing protein gel electrophoresis (1D and/or 2D)	☐	☒
Experience of concentrating samples	☐	☒
Non-academic analytical laboratory experience	☐	☒
Experience of working to the requirements of a quality system such as ISO9001 or GMP. Up-to-date knowledge of regulatory guidance and requirements for biopharmaceuticals.	☐	☒
Skills and capabilities		
Ability to prioritise and plan own work.	☒	☐
Good written and verbal communication skills	☒	☐
Proficiency in MS Office and other relevant software	☒	☐
Problem solving / troubleshooting skills	☒	☐
Technical report writing skills	☒	☒
Effective presentation of work to internal and external customers	☒	☐
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:	