Job description

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

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range 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's Anthrax Vaccine as well as providing R&D services for product development.

The Development Group, with in PBL, is a development and technology transfer Group playing a key role in the translational research activities of the site. Its role is to develop manufacturing processes and associated analytical methods for use in the cGMP production of biotherapeutics and healthcare interventions. The projects may comprise the development of research designs and/or the improvement of existing commercial processes. The group is organized into 3 core teams with responsibility for upstream processes, downstream processes and analytical methods development respectively.

JOB SUMMARY

The post-holder will contribute to the income generating activities of the group by providing technical support in the development of manufacturing processes for biopharmaceutical products within Fermentation/ Upstream Process Development laboratories. The post holder will be knowledgeable in innovation, development and scale-up of microbial fermentation processes, handling of pathogenic/non-pathogenic microorganisms, various molecular techniques, *in-vitro* testing of vaccines, microbial assay development, Design of Experiment methodology. They will be required to work in multi-disciplinary teams to deliver key business objectives. They will contribute to the generation of experimental designs, presentation of work to internal and external customers and the preparation of scientific publications, technical reports and project proposals. The post holder will contribute to process validation and manufacture problem solving and technology transfer activities relating to the development and/or manufacture of biopharmaceutical products internally or between Porton Biopharma and its collaborators/customers.

The post holder will be responsible for training staff within the area of specialism and supervising operational laboratories ensuring that work is undertaken to Porton Biopharma quality and safety policies. When required they will work to the requirements of European and US cGMP. Additionally, the post holder will be required to maintain an interest in and actively seek out

innovations through collaborations within and outside the organization as necessary to benefit the project and/or department.

Communication and key working relationships

Internal

- Department heads, Operational managers, Project leader, Project teams, other parts of Porton Biopharma e.g. Safety, Business development, Manufacturing and Quality.

External

- Academic researchers, Scientists, Customers, Regulatory Authorities and Suppliers.

MAIN DUTIES AND RESPONSIBILITIES

- Be accountable to the relevant Team Lead for the day to day operations of the Upstream/ Fermentation Development areas.
- To provide expert scientific and technical specialism in the area of Fermentation processing to projects involved in the improvement of existing and development and manufacture of new biopharmaceutical products.
- Be knowledgeable in the area of Quality by Design/ Design of Experiments, fermentation process and media development, scale-up and validation.
- Prepare project plans, monitor and report progress against agreed timelines as required by Project leads.
- Assist senior colleagues in project related tasks.
- Generate experimental designs, perform experimental work, analyse and manage data and prepare project reports, scientific publications etc.
- Perform small scale shake flask experiemnts as well as scale up using fermenters.
- Take responsibility for the supervision of laboratory facilities including maintenance and servicing of equipment and facilities, provision of reagents / consumables required for the project.
- Ensure that the project work is performed in accordance with the organisation's Code of Safety Practice and to work within Quality Systems.
- Assist, as required, in the technology transfer of information relating to the development and/or manufacture of biopharmaceutical products internally or between Porton Biopharma and its collaborators/ customers.
- Be responsible for the training and development of staff within the area of specialism.
- Maintain awareness of Porton Biopharma cGMP requirements and apply that understanding to the development of processes for new biopharmaceutical products.
- Participate in the development and validation of production and analytical methods for cGMP biopharmaceuticals.
- Actively seek out innovations through collaborations within and outside the organisation as necessary to benefit the project and/or department.
- Assist senior colleagues in developing scientific and technical strategy of the project or derived projects, identifying new opportunities as they arise and responding to funding calls or customer enquiries.
- To comply with all Porton Biopharma policies and procedures.
- To perform any other duties required by the Line manager commensurate with 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		
BSc in biological sciences/ microbiology/ biochemistry/ biotechnology/ bio-medical sciences	☒	☐
Higher degree; MSc/ PhD in a related discipline	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Several years relevant laboratory experience of microbial fermentation processes and media development (small scale to pilot scale)	☒	☐
Good experience of strain development, molecular techniques and general recombinant DNA technology	☒	☐
Experience of data analysis and use of statistical tools	☒	☐
Experience of working within a commercial biopharmaceutical environment	☐	☒
Technology transfer & Process validation experience	☐	☒
Demonstration of external collaborations and pipeline generation	☐	☒
Participation in multidisciplinary project teams	☐	☒
Understanding of cGMP and Health & Safety regulatory requirements	☐	☒
Skills and capabilities		
Technical writing of protocols, procedures, scientific publications and project reports.	☒	☐
Working to a quality/safety systems	☒	☐
Good oral and written communication skills	☒	☐
Ability to work in project teams	☒	☐
Delivery of project milestones to agreed timescales	☒	☐
Problem solving and troubleshooting skills	☒	☐
Experience in planning and prioritizing	☒	☐
Good organizational skills	☒	☐
Attention to detail	☒	☐
Self-motivated, 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:	