PORTON BIOPHARMA

Job description

Job title	Fermentation Development Lead
Directorate	Development
Pay band	Career Level 3
Responsible to	Head of Fermentation Development
Base/location	Porton Biopharma Ltd.
Hours/sessions per week	37.5hours
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 company carries out the manufacture of Erwinase and Anthrax Vaccine as well as contract manufacturing projects.

Development is a directorate of PBL and is a development and technology transfer Group playing a key role in the translational research activities of the company. Its role is to develop manufacturing processes and associated analytical methods for use in the cGMP production of bio-therapeutics and healthcare interventions. Development projects may comprise the development of research designs and/or the improvement of existing commercial processes. The Development Group is organized into 3 core teams responsible for *in vitro* culture processes, downstream processes and analytical methods development respectively

JOB SUMMARY

The post is part of the Fermentation Development Team. The post holder will take the lead in the activities relating to the development of fermentation processes, in particular those related to the culturing and processing of pathogenic microorganisms. The post holder will also be responsible for supporting the head of the Fermentation Development in operational activities. This includes, but not solely limited to, recruitment, line management, staff performance, appraisals, supervision and training of the staff.

The post holder will also be responsible for the preparation of project proposals for customers, and implementation of same, together with production and review of reports and presentation for both internal and external customers. Additionally, the post-holder will be required to maintain an interest in and investigate potential new products/ processes which may be of interest to the development of the directorate. The post-holder will maintain up-to-date knowledge of all required regulatory guidelines.

They will provide a scientific and technical specialism in the area of Fermentation to projects involved in the development of processes for the manufacture of biopharmaceutical products and will be required to work in multi-disciplinary teams, leading as required to deliver key

objectives. They will lead in the generation of experimental designs, presentation of work to internal and external customers and the preparation of scientific publications, technical reports and project proposals. They will play a key role in the technology transfer activities relating to the development and/or manufacture of biopharmaceutical products internally or between Porton Biopharma and its collaborators/customers.

Communication and key working relationships

Internal

- Directorate Heads, Head of Fermentation Development, Operational Managers, Project Managers, 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

1. Be accountable to the Head of Fermentation Development for leading the fermentation development projects.
2. Support the Head of Fermentation Development to manage the activities dedicated to the development of GMP and non-GMP fermentation processes.
3. Be responsible for the line management of junior staff including scientific management, performance management, supervision and training.
4. 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.
5. To act as principal investigator/lead specialist of the project teams taking lead responsibility to deliver key objectives and identify, evaluate and adapt new technologies where appropriate and to ensure that projects operate to a high scientific standard using current methods.
6. Be knowledgeable in the area of Quality by Design/ Design of Experiments, fermentation process and media development, scale-up and validation.
7. Play a key role in the technology transfer activities relating to the development and/or manufacture of biopharmaceutical products internally or between Parton Biopharma and its collaborators/customers.
8. Assist senior management 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.
9. Take responsibility for the initiation and implementation of research and development activities for new projects within the area of expertise.
10. Provide reports as required and lead on preparation of project proposals, presentations, publications and liaison with the customer as well as dealing with enquiries as necessary.
11. To critically review internal and external technical documents.
12. Prepare project plans, monitor and report progress against agreed timelines as required by Project Managers.
13. To contribute to or take the lead on publications in national and international journals.
14. To ensure that project teams undertake work in accordance with the organisation's Code of Safety Practice and to work within any Quality Systems that are applicable to the site.
15. Maintain an awareness of cGMP and other regulatory requirements and apply that understanding in the development and technology transfer of processes for new pharmaceutical products.
16. To comply with all PBL policies and procedures.
17. Deputise, when required, for the Head of Fermentation Development

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.

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Person specification

Description	Essential	Desirable	Assessment
Qualification			
Higher degree in a relevant scientific discipline - MSc or equivalent	x		C,A,I
PhD in a biochemical/ biotechnological discipline		x	C,A,I
Knowledge and experience			
Several years relevant laboratory experience with practical knowledge of QbD, DOE, fermentation processes and media development, scale-up, and analytical methods	x		A,I
Experience of working within a commercial scientific environment		x	A,I
Experience in handling of pathogenic microorganisms and toxic products		x	A,I
Experience in managing teams	x		A,I
Technology transfer & Process validation experience		x	A,I
Participation in multidisciplinary project teams	x		A,I
Understanding of GMP and other regulatory requirements		x	A,I
Skills and capabilities			
Significant leadership skills		x	A,I
Technical writing of protocols, scientific publications, project reports	x		A,I
Working to a Quality/safety system	x		A,I
Good oral and written communication **skills**	x		A. I
Ability to work in project teams and to plan own and others work	x		A,I
Delivery of project milestones to agreed timescales	x		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	x		I

***Assessment will take place with reference to the following information**

A= Application form	**I= Interview**	**C = Certificate**	**T = Test**

Job description agreed with post holder

Employee signature: …… Date:……

Print name:

Manager's signature:……Date:.....

Print name: