Job description

Job title	Senior Process Development Scientist
Directorate	Development
Career Level	Level 4
Responsible to	DSP Innovations Lead
Base/location	Porton Biopharma
Hours/sessions per week	37.5 hours per week
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 plays 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 bio therapeutics and healthcare interventions. Projects may comprise the development of research designs and/or the improvement of existing commercial processes. The Development Group is organized into 4 core teams responsible for in vitro culture processes, downstream processes, analytical method development and product development respectively.

JOB SUMMARY

The post-holder will contribute to the income generating activities the Development Group by providing technical support in the development of manufacturing processes for biopharmaceutical products within ISO 9001 laboratories.

He/she will provide a scientific and technical specialism in the area of Downstream Processing to projects involved in the development of processes for the manufacture of biopharmaceutical products. The post holder will be knowledgeable in the area of Quality by Design/Design of Experiments, protein purification, process development, scale-up and validation. They will be required to work in multi-disciplinary teams, leading as required to deliver key 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 activities and 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.

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 cGMPs. 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, Research and Quality.

External

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

MAIN DUTIES AND RESPONSIBILITIES

1. Be accountable to the Downstream Innovation Lead/Development and Scale-up Lead for the day to day operations of the Downstream Development areas.

2. Provide scientific and technical specialism in the area of Quality by Design, Design of Experiments, protein purification, process development, scale-up and validation to projects involved in the development of processes for the manufacture of biopharmaceutical products.

3. Maintain awareness of Porton Biopharma cGMP requirements and apply that understanding to the development of processes for new biopharmaceutical products.

4. Actively seek out innovations through collaborations within and outside the organisation as necessary to benefit the project and/or department.

5. Play a key role 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.

6. Be responsible for the training and development of staff within the area of specialism.

7. Assist senior colleagues, leading where necessary, 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.

8. Provide reports as required and lead on preparation of presentations and liaison via teleconferences with the customer as well as dealing with enquiries as necessary.

9. Prepare project plans, monitor and report progress against agreed timelines as required by Project leads.

10. Take responsibility for the supervision of laboratory facilities including provision of reagents and consumables required for the project and documented storage of materials generated.

11. To ensure that the project team undertakes work in accordance with the organisations Code of Safety Practice and to work within any Quality Systems that are applicable to the site.

12. To comply with all Porton Biopharma policies and procedures.

13. 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.

Person specification

Description	Essential	Desirable	Assessment
Qualification			
BSc in biological sciences/ biochemistry/ biotechnology/bio-medical sciences	☒	☐	C,A,I
PhD/MSc in a biochemical/biotechnological discipline	☐	☒	C,A,I
Knowledge and experience Experience as defined by type/level (not length)			
Several years relevant laboratory experience with practical knowledge of Quality by Design, Design of Experiments, protein purification, development, scale-up, protein characterization and analytical methods.	☒	☐	A,I
Experience of working within a commercial scientific environment	☒	☐	A,I
Demonstration of external collaborations and pipeline generation	☒	☐	A,I
Technology transfer & Process validation experience	☒	☐	A,I
Participation in multidisciplinary project teams	☐	☒	A,I
Understanding of GMP and other regulatory requirements	☐	☒	A,I
Skills and capabilities			
Technical writing of protocols, scientific publications, project reports	☒	☐	A,I
Working to a quality/safety systems	☒	☐	A,I
Good oral and written communication skills	☒	☐	A,I
Ability to work in project teams and to plan own and others work	☒	☐	A,I
Delivery of project milestones to agreed timescales	☒	☐	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	✓		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:…….....…