Job description

Job title	Aseptic Processing Specialist
Directorate	Production
Career level	3
Responsible to	Aseptic Processing Functional Manager
Base/location	Porton
Hours/sessions per week	37.5
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.

JOB SUMMARY

This position will report to the Aseptic Processing Functional Manager, and will provide technical specialist support to all aseptic processing activities in the manufacture of Erwinase, Anthrax vaccine and other PBL products. The role will work cross functionally and be involved in current projects, new projects and all manufacturing activities that require aseptic processing input. It is expected that the role will typically focus on day to day aseptic processing matters within Production but may also be required to support projects designed to improve and develop PBL's aseptic processing strategy.

Communication and key working relationships

Internal

- Executive Managers
- Unit Managers
- Production Team Lead and Supervisory staff
- Production Technicians
- Technical Support
- Process Development
- QA
- QC Microbiology

External

- Regulatory Agencies
- Customers
- Suppliers
- Contractors

MAIN DUTIES AND RESPONSIBILITIES

- Leading in the day to day aseptic processing of PPL's products.
- Support the management and development of improved and new processing techniques in the various aseptic processing activities.
- Provide technical support to production staff involved in the various aseptic processes.
- Troubleshooting and technical support into process investigations.
- Collate and share technical information with internal and external bodies to benefit the production methods, teams and departments.
- Perform process mapping and process efficiency trending.
- Provide specialist training to staff in aseptic processing techniques and theory.
- Identify, evaluate and adapt new technologies where appropriate and ensure that the production area operates to a high standard and complies with GMP and other regulatory standards.
- Assist colleagues in providing technical specialist input as required, in developing production and technical strategies for the units, identifying new opportunities as they arise and responding to external queries and complaints.
- Contribute to reports and assist on the preparation of presentations, publications and liaison with customers, collaborators and licensing agencies.
- Support the Functional Manager Aseptic Processing in pursuance of strategic improvements to aseptic processing control.

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 or equivalent in an appropriate discipline	☐	☒	A, I
Knowledge and experience Experience as defined by type/level (not length)			
Previous relevant industry experience	☒	☐	A, I
Specific training and experience in Aseptic production methods in a pharmaceutical environment	☒	☐	A, I
Extensive GMP production experience	☒	☐	
Understanding of regulatory requirements for biological products	☒	☐	
Experience in the implementation of new technologies and equipment into GMP manufacture	☒	☐	
Skills and capabilities			
Delivery to schedules	☒	☐	A, I
Aseptic processing technology experience	☒	☐	A, I
Delivery of specialised technical training	☐	☒	
Report writing and data trending evaluation	☐	☒	
Experience of generating GMP documents within the Quality System	☒	☐	
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:…….....…