

Job description

Job title	Senior Production Technician - PPC Zones 1-4
Directorate	Production
Career Level	5
Responsible to	Unit Supervisor
Base/location	Porton Down
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.

PPC Zones 1-4 is dedicated to the manufacture of Erwinase within two manufacturing sub units the Therapeutics Protein Unit (TPU) and Product Finishing Unit (PFU), both units are GMP manufacturing facilities. TPU performs downstream purification of the therapeutic products and PFU performs aseptic processing and final fill of the product. The post holder will report to the PPC Zones 1-4 Unit Manager.

JOB SUMMARY

This post is part of the team within the manufacturing area responsible for the downstream processing, formulation and filling and freeze drying of Erwinase. The team is responsible for the production of pharmaceutical products, preparation of components and the operation of production equipment. Day to day tasks also include maintaining the facility via specialist cleaning procedures, monitoring environmental conditions and performing aseptic processes within a cleanroom environment.

Communication and key working relationships

Internal

- Manufacturing, Operational Project Management, Quality, Safety, Validation, HR, Finance, Emcor, Facilities Management

External

- Specialist Contractors, suppliers, consultants, DEFRA, BSI, Commercial customers.

MAIN DUTIES AND RESPONSIBILITIES

- Be responsible to the Unit Supervisor for your day to day activities.
- Undertake all work in accordance with Code of Safety Practice, Quality System and all other regulatory requirements.
- Follow all Procedures, Policies, Rules, Regulations and Guidelines for all activities to ensure products meet the required standard.
- Always take care and pay detailed attention to all tasks.
- Complete documentation and records accurately and to a high standard.
- Work to cGMP ensuring the unit is maintained in a compliant state following Standard Operating Procedures (SOPs) and codes of practice. Keep updated on new rules and regulations.
- Maintain production areas to the required standard using defined cleaning procedures.
- Perform and record environmental monitoring in cGMP areas in accordance with documented procedures. Take waters samples and complete relevant documentation. Monitor and record air pressures and hot and cold facility temperatures.

PRODUCTION RESPONSIBILITIES

- Perform a wide range of routine and some non-routine technical procedures and understand the rationale behind the procedures and practices.
- Maintain and use a variety of laboratory equipment.
- Work with a range of hazardous and non-hazardous chemicals.
- Be competent to work in a clean room environment
- Work accurately with good hand eye co-ordination. Sometimes for prolonged periods of time.
- To assist in activities relating to the cGMP manufacturing of pharmaceutical products i.e. Prepare media, buffers and reagents both sterile and non-sterile. Packing and sterilisation of general and specialised equipment.

GENERAL RESPONSIBILITIES

- Work as part of a team.
- Undertake general housekeeping duties e.g. rotation of stock, preparation of cleanroom clothing, cleaning of glassware and equipment.
- Stock control of consumable. Order consumables from internal stores and external suppliers.
- Communicate effectively with a variety of staff in a range of matters. To give, receive and relay information.
- Liaise with other production areas to ensure efficient running of the unit.

- On occasion the post holder may be requested to work overtime.

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
Eligibility			
Current & Valid Right to work in the UK	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A,I
Qualification			
GCSE (Grades A – C) in Maths, English and Science	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A
Knowledge and experience Experience as defined by type/level (not length)			
Knowledge of cGMP requirements and how to implement them	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Accurate and clear record keeping skills.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Good numeracy skills	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Organised methodical approach	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Able to work to strict deadlines	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Experience of working in a food industry or laboratory environment	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Experience of working in a health care environment.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Working knowledge of Microsoft Office including Word and Excel.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Ability to follow established written procedures.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A/I
Understanding/know-ledge of clean room procedures/GMP	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Experience with the operation of specialised equipment.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A/I
Understanding of the various relevant regulatory requirements.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	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	<input checked="" type="checkbox"/>		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:.....