Job description

Job title	Senior Production Technician
Directorate	Production
Pay band	Career Level 5
Responsible to	FPP Compliance Team Supervisor
Base/location	FPP Compliance office
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd, Porton Down has approximately 300 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.

The Senior Production Technician post is located at the Fermentation Process Plant (FPP) at Porton Down. The FPP is an FDA and MHRA licensed GMP manufacturing facility which produces therapeutic products by bacterial fermentation, then extracts the active ingredient from the fermentation by initial phase downstream processing

JOB SUMMARY

The successful candidate will be responsible for ensuring that BMRs are available for production use; raw materials are ordered and available for production use and completing preparation of production samples for QC testing as well as ensuring post manufacture, batch records are collated, results transcribed and initial review performed prior to sending to Quality.

Communication and key working relationships

Internal

- Team peers, Production Management, Pharmaceutical Stores, Quality Assurance

External

Suppliers for ordering of consumables.

MAIN DUTIES AND RESPONSIBILITIES

- Responsible for the timely supply of GMP documentation for production of Erwinase fermentation and extraction to meet agreed production schedules.
- Responsible for the timely supply of raw material for GMP production. Ensuring stock rotation and availability of consumables.
- Maintain GMP databases in a timely manner.
- Downloading and archiving of Data Monitoring Systems (DMS) throughout the GMP FPP manufacturing area.
- Preparation, labelling and documentation preparation of Erwinase production samples prior to QC testing.
- Ensure compliance is maintained during manufacture and that PBL policies and procedures are applied when necessary.
- Liaise with Pharmaceutical Stores, QC, Product Release, EMCOR to ensure the unit stays within compliance and is ready for operations when required.
- Ensuring training is completed and up to date for their required area of work.

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 plan 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			
Educated to A level in biological sciences discipline or significant related experience.	☐	☒	A,I, C
GCSE in Maths, English & Science or equivalent.	☒	☐	A,I
Knowledge and experience Experience as defined by type/level (not length)			
Previous experience of working in a GMP biopharmaceutical manufacturing facility	☐	☒	
Experience of documentation review	☒	☐	A,I
Experience of databases including Word and Excel.	☒	☐	A,I
Experience of ordering, stock control and rotation	☒	☐	A,I
Experience of working within a team of technical staff	☒	☐	A,I
Skills and capabilities			
Experience of working in multidisciplinary teams and ensuring compliance within a pharmaceutical manufacturing environment	☒	☐	A,I
Problem solving skills	☒	☐	A,I
Motivated to work on own initiative, organising and prioritising own workload to meet deadlines	☒	☐	A,I
An ability to maintain confidentiality and trust.	☒	☐	A,I
Clear communicator with good writing, data entry and telephone skills.	☒	☐	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:…….....…