Job description

Job title	Senior Production Technician (Compliance)
Division	Production
Career Level	5
Responsible to	Unit Manager

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range development and manufacturing roles for biopharmaceuticals. This also includes all associated support functions from logistics through to engineering, quality control / quality assurance, regulatory affairs and management. The Company manufactures two licensed products, Erwinase® and the UK's Anthrax Vaccine as well as providing R&D services for product development.

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. Post manufacture, batch records are collated, results transcribed and initial review performed prior to sending to Quality.

Communication and key working relationships

Internal

- Production Teams
- Production Management
- QA
- QC
- Pharmaceutical Stores

External

- Suppliers

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.

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.

Applicants must hold or be capable of obtaining a UK government security clearance at SC level.

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.

You should adhere PBL values and behaviors:

- Passion
- Respect
- Integrity
- Diligence
- Excellence in Execution (E^2)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	☒	
A good standard of written and spoken English Language	☒	
Qualification		
Educated to A level in biological sciences discipline or significant related experience.	☐	☒
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	☒	☐
Experience of databases including Word and Excel.	☒	☐
Experience of ordering, stock control and rotation	☐	☒
Experience of working within a team of technical staff	☐	☒
Skills and capabilities		
Experience of working in multidisciplinary teams and ensuring compliance within a pharmaceutical manufacturing environment	☐	☒
Problem solving skills	☐	☒
Motivated to work on own initiative, organising and prioritising own workload to meet deadlines	☒	☐
An ability to maintain confidentiality and trust.	☒	☐
Clear communicator with good writing, data entry and telephone skills.	☒	☐
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	☒	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	