Job description

Job title	Senior Production Technician Visual Inspection Team
Directorate	Production
Career Level	5
Responsible to	Visual Inspection Supervisor
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.

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 PFU Supervisor.

JOB SUMMARY

This GMP post is part of the team within the Pharmaceutical Production Centre responsible for Visual Inspection of vials of Erwinase with additional duties including media and equipment preparation, assisting with purification and formulation of Erwinase Drug Substance, sterile filtration, filling and freeze drying of Erwinase and aseptic processing. Day to day tasks also include maintaining the facility via specialist cleaning procedures and monitoring environmental conditions within a cleanroom environment.

Communication and key working relationships

<u>Internal</u>

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

External

- Contractors, Suppliers and Consultants.

MAIN DUTIES AND RESPONSIBILITIES

- Support junior staff in their activities and ensure they are adequately trained in all operational processes required.
- Be responsible to the Unit Supervisor for the day to day operations of the Unit and, if required, to deputise in their absence.
- Undertake all work in accordance with the 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.
- Generate documentation with regard to risk assessments and cGMP to ensure compliance of the Unit with all necessary regulations.
- 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 (SOP's) 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.
- Analyse information and make decisions based on assessment.
- Execute Validation Protocols on equipment.
- 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.

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			
GCSE Mathematics, English & Science.	☒	☐	A/C
Educated to minimum of NVQ 2 level in a relevant subject or equivalent level of qualification or significant equivalent proven experience.	☒	☐	A/C
Knowledge and experience Experience as defined by type/level (not length)			
Knowledge of working in a GMP manufacturing environment.	☒	☐	A/I
Experience of operating specialized equipment	☒	☐	A/I
Experience of working to deadlines or schedules	☒	☐	A/I
Experience of working in a Cleanroom environment	☐	☒	A/I
Ability to follow written procedures	☒	☐	A/I
Understanding of regulatory requirements for GMP manufacture	☐	☒	A/I
Skills and capabilities			
Good communication and telephony skills	☒	☐	A/I
Accurate writing and data entry skills	☒	☐	
Ability to work effectively as part of a team.	☒	☒	A/I
Flexible approach to work.	☒	☐	A/I
Problem solving skills.	☐	☒	A/I
Be proactive and able to work on own initiative, organising and prioritising own workload to set deadlines.	☒	☐	I
Excellent near sight vision	☒	☐	Opticians assessment
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:…….....…