Job description

Job title	Unit Supervisor
Directorate	Production
Pay band	EO
Responsible to	Unit Manager/Team Leader
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 process and analytical development, production, quality control and quality assurance roles associated with the development and manufacture of biopharmaceuticals.

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 filling, freeze drying and visual inspection of the product.

JOB SUMMARY

The post holder will be responsible for the day to day support and management of junior staff in the income generating activities of Porton Biopharma Ltd (PBL) by providing a technical lead in the manufacture of biopharmaceutical products within a GMP/ISO-9001 production facility.

The post holder will be responsible for ensuring the facility is maintained in a GMP compliant state, and that all staff adhere to, and all operations are carried out to, strict GMP guidelines.

Communication and key working relationships

Internal

- Production Management
- Quality Assurance
- Quality Control
- Engineering
- Safety

- HR
- Facilities Management

External

- Suppliers
- Specialist contractors
- Consultants
- Commercial customers
- Regulatory bodies

MAIN DUTIES AND RESPONSIBILITIES

- To carry out duties involved in the manufacture of biopharmaceuticals to GMP and ISO 9001 requirements as directed.
- Ensure that the facility is maintained in a compliant state and that the product/materials are manufactured to appropriate regulatory requirements.
- Responsible for the provision of all consumables, supplies, etc. required for the process and documented storage of materials generated.
- Manage and support junior staff in all their activities and ensure they are adequately trained in all operational processes.
- Responsible for ensuring that all staff adhere to, and all operations are carried out to, strict GMP guidelines.
- To undertake all necessary training to enable the post holder to carry out his/her duties to the required standard.
- Assist the Unit Manager/Team Leader in the completion of annual and six-monthly staff appraisals.
- Generate and review documentation with regard to risk assessments and cGMP, e.g. SOPs, to ensure compliance of the Unit with all necessary regulations. Complete documentation and records accurately and to a high standard.
- To assist in the timely closure of non-conformances, CAPAs and change controls.
- Work accurately with good hand and eye co-ordination, sometimes for prolonged periods of time.
- Required to work extended hours on critical processing days.
- Perform a wide range of routine and some non-routine technical procedures and understand the rationale behind the procedures and practices.
- To undertake work in accordance with PBL Health and Safety Policies and procedures and to work within any Quality systems that are appropriate to the site.

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	√		A/I
Good standard of written and spoken English Language	√		A/I
Qualification			
HNC or equivalent qualification or extensive significant GMP production experience	√		A/I
Supervisory or management qualification		√	A/I
Degree or equivalent qualification in a relevant subject		√	A/I
Knowledge and experience Experience as defined by type/level (not length)			
Experience with the operation of specialised equipment	√		A/I
Knowledge of cGMP requirements and how to implement them	√		A/I
Understanding of various regulatory requirements		√	A/I
Substantial experience in a supervisory role	√		A/I
Significant experience in a relevant technical area	√		A/I
Hands-on experience preparing large volumes of documents		√	A/I
Completed courses to GMP standards		√	A/I
Experience of training staff	√		A/I
Skills and capabilities			
Good communication and interpersonal skills	√		A/I

Ability to work effectively as part of a team	√		A/I
Accurate and clear record keeping skills	√		A/I
Ability to work on own initiative and prioritise workload with minimal supervision working to tight and often changing timescales	√		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:…….....…