Job description

Job title	Unit Manager - Immuno
Directorate	Production
Career Level	3
Responsible to	Deputy Head of Pharmaceutical Production
Base/location	Pharmaceutical Production Centre (PPC)
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.

The Unit Manager post is located at the various Production Centres at Porton Down. The facilities are FDA and MHRA licensed GMP manufacturing units which produce a number of healthcare products.

JOB SUMMARY

The Unit Manager post is located at the various Production Centres at Porton Down. The facilities are FDA and MHRA licensed GMP manufacturing units which produce a number of healthcare products.

Communication and key working relationships

Internal

- Direct reports, Production Management, Safety, Quality Assurance, Quality Control, Engineering and Validation, HR

External

- Contractors, Suppliers, Customers and Regulators.

MAIN DUTIES AND RESPONSIBILITIES

- Implement and utilise a range of production methods and procedures in support of all activities associated with manufacturing.
- To ensure the facilities are maintained and fit for purpose.
- Ensure all support activities including Engineering and Validation, required to ensure GMP compliance are scheduled and executed.
- Supervision and training of staff
- Responsible for the generation of Non- Conformances, CAPAs, Risk Assessments and Change Controls
- Ensure the unit is ready at all times for audit by any regulatory organisation
- Responsible for the provision of all consumables and, supplies required for day to day activity.
- Identify, evaluate and adapt new technologies where appropriate and ensure that the production area operates to a high standard and complies with GMP and other regulatory standards.
- Provide reports on all aspects of manufacturing as requested.

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			
Right to work in the UK	☒	☐	
A good standard of written and spoken English Language	☒	☐	
Qualification			
Degree in a relevant subject or evidence of work experience in pharmaceutical production	☐	☐	A/I/C
Knowledge and experience Experience as defined by type/level (not length)			
Management/Team leader role in GMP manufacturing environment	☒	☐	A/I
Preparation of batch documentation and SOPs	☒	☐	A/I
Downstream processing experience	☐	☒	A/I
Experience of managing teams of technical staff	☒	☐	A/I
Batch and facility planning to support schedules	☒	☐	A/I
Monitor, adjust and ensure compliance with schedules	☒	☐	A/I
Comprehensive understanding of critical utilities, calibration, Validation, and maintenance activity associated with a GMP environment.	☒	☐	A/I
Experience of managing Master and Working Cell Banks	☐	☒	A/I
Experience in ACDP containment work processing in biopharmaceuticals	☒	☐	A/I
Experience/training in clean room environment	☒	☒	A/I
Experience with Aseptic techniques	☐	☒	A/I
Experience with staff assessments and appraisals	☐	☒	A/I
Skills and capabilities			
Current Guidelines and Regulations	☒	☐	A/I
Successful introduction of new technologies	☐	☒	A/I
Work on own initiative and prioritise workload and deadlines	☒	☐	A/I
Able to chair meetings.	☒	☐	A/I
Suitable judgement required to identify areas for escalation	☒	☐	A/I
Ability to resolve complex multi layered problems	☒	☐	A/I

Skills and capabilities continued ….			
Ensure Health and Safety guidelines for a SAPO working environment are followed	☐	☒	A/I
Ability to work in different areas at short notice	☒	☐	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:…….....…