Job description

Job title	Calibration Supervisor
Division	Engineering
Career Level	3
Responsible to	Instrumentation 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 PBL Engineering group is responsible for provision of all engineering support within the highly regulated GMP Facilities at PBL Porton Down. This structure includes engineering functions provided by professional engineers specialising in clean rooms, GMP critical utilities, production equipment, pharmaceutical facilities, and capital works delivery.

JOB SUMMARY

Lead, motivate and manage the development of the Pharmaceutical Engineering Calibration Team and provide expertise in a cross functional group responsible for the delivery of compliance within Porton Biopharma (PBL). The post holder also has overall management responsibility for external service providers contracted to PBL specifically to deliver specialized support in the service of critical facilities and equipment.

The post holder will ensure all calibration activities under the position's responsibility are delivered in a timely manner in order to prevent delay to production.

Communication and key working relationships

<u>Internal</u>

- Manufacturing
- Capital Projects
- Principle Maintenance Contractor
- Validation
- Quality
- Safety

- HR
- Asset Owners
- Scheduling

External

- Specialist Contractors
- Suppliers
- Consultants
- MHRA
- FDA

MAIN DUTIES AND RESPONSIBILITIES

- Lead, motivate and manage the development of the Pharmaceutical Engineering Calibration Team and provide expertise in a cross functional group responsible for the delivery of compliance within Porton Biopharma (PBL).
- Day to day management of calibration activities and associated resource planning to meet the requirements of defined schedules through weekly scheduling meetings and shutdown meetings.
- Completion of calibration assessments.
- Generation of non-conformance documentation.
- Lead the development and implementation of quality improvement plans to maximize the efficiency of the Calibration Team.
- Carry out all duties within the PBL and PHE and specific safety and Quality Policies.
- Ensure adequate Calibration, Instrumentation and automation procedures and processes are in place to meet the business, GxP quality system and regulatory requirements.

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.

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 degree level in a life/applied science subject or equivalent level qualification or significant experience of working at a similar level in delivery of calibration services.	☒	☐
Extensive experience in an Engineering operational role in the Pharmaceutical Industry.	☐	☒
Effective leadership and planning skills.	☒	☐
Experience of Regulatory Audits.	☐	☒
Experience in Preparing Detailed GMP Engineering Technical Documentation.	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Extensive Practical, pharmaceutical industry experience of GMP facilities and equipment.	☒	☐
Experience of current available Pharmaceutical Instrument technology and its subsequent sizing/selection to support Pharmaceutical Operation.	☐	☒
Experience of working within a GMP Quality System, in particular, change control, Non-Conformance management, CAPA, discrepancy/deviation, and documentation management.	☒	☐
Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction.	☒	☐
Skills and capabilities		
Accurate and clear record keeping.	☒	☐
Wide GMP experience.	☒	☐
Specialist knowledge of Calibration of equipment relating to GMP pharmaceutical production Facilities.	☐	☒
Report writing.	☒	☐
Diplomatic and tactful approach to colleagues and good communication skills.	☒	☐
Excellent organisational skills.	☒	☐
Quality focus.	☒	☐
Computer skills.	☒	☐

Numeracy.	☒	☐
Knowledge and Operation of Computerised Maintenance Management Systems (Maximo).	☐	☒
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:	