Job description

Job title	Calibration Supervisor
Directorate	Production
Pay band	Career Level 3
Responsible to	Instrumentation Manager
Base/location	Porton
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma, Porton Down has approximately 300 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The department carries out the manufacture of Erwinase and Anthrax as well as contract manufacturing projects.

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 will ensure all calibration activities under the positions responsibility are delivered in a timely manner in order to prevent delay to production.

Communication and key working relationships

Internal

- Manufacturing
- Scheduling Team
- FM Capital Projects
- Principal Maintenance Contractor
- Operational Project Management
- Quality
- Safety
- Validation
- HR

External

- Specialist Contractors
- Suppliers
- Consultants
- BSI
- 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.
- Coordination of access with Scheduling Team.
- Generation of Isolation Requests.
- Generation of non-conformance documentation.
- Train Calibration Technicians in local calibration procedures.
- 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 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.

Person specification

Description	Essential	Desirable	Assessment
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.	✓		A, I
• 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	✓	✓ ✓ ✓	A, I
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 Operations • 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	✓ ✓ ✓	 ✓ 	A, I
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	✓ ✓ ✓ ✓	 ✓ 	A, I

• Excellent organisational skills • Quality focus • Computer skills • Numeracy • Knowledge and Operation of Computerised Maintenance Management Systems (Maximo)	✓ ✓ ✓ ✓	✓	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:…….....…