Job description

Job title	Process Engineer
Division	Engineering
Career Level	3
Responsible to	Ian King

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 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 predominantly chartered professional engineers specialising in clean rooms, GMP critical utilities, production equipment, pharmaceutical facilities, and capital works delivery.

JOB SUMMARY

[The Process Engineer is the principal engineering representative within a multidisciplinary Integrated Process Team (IPT) alongside colleagues drawn from the Engineering, Quality and Production groups. They will be responsible for providing technical engineering expertise across a range of equipment and systems used by PBL in the manufacture of pharmaceutical products, for example fermenters, vessels, autoclaves, ovens and purified water, Water For Injection and clean steam systems. They will take the lead role in for coordinating the response of the Engineering department to equipment failure within their IPT and to the delivery of reactive remedial works, including the clear communication of issues and status to stakeholders at all levels of the organisation. They will additionally be responsible for the identification and delivery of small process improvement initiatives relating to equipment and systems within their IPT. The Process Engineer will interface with the PBL Quality System to ensure that process equipment and utility systems within the GMP envelope remain compliant with current Good Manufacturing Practice.

Communication and key working relationships

<u>Internal</u>

- Manufacturing
- Engineering & Calibration
- Capital Projects
- Operational Project Management
- Quality
- Safety
- Validation
- HR

External

- Specialist Contractors
- Suppliers
- Consultants
- Regulators

MAIN DUTIES AND RESPONSIBILITIES

- To represent and provide a main point of contact for the Engineering function within the IPTs
- To lead the troubleshooting of faults with equipment and systems used within the IPT, establishing and addressing root causes, provide options and solutions to identified problems, whilst ensuring appropriate communication with stakeholders and maintaining compliance with the requirements of cGMP.
- To lead the investigation and root cause analysis determination of deviations within integrated process teams (IPTs) through the PBL non conformance system
- Project manage the implementation of process improvements and/or CAPA actions through the delivery of small GMP capital projects in accordance with the PBL GMP Capital Project procedure.
- To oversee the monitoring the performance of equipment and systems supporting manufacturing including critical utilities, identifying opportunities for process improvement.
- To generate, review and approve technical engineering documentation relating to quality and safety e.g. specifications, protocols, reports and technical drawings
- Where able to act as a subject matter expert, to provide practical or technical training in applicable Engineering SOPs and associated documents to PBL staff both inside and outside of the engineering group
- Where necessary to represent Engineering as project engineer/ technical specialist on process related capital projects. This will include providing practical input into concept design, design reviews, participating in Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT) and the execution of equipment qualification for new equipment and systems
- With the support of the Process Engineering Manager and the Director of Engineering to represent the Engineering function at MHRA and FDA audits as a subject matter expert for process engineering

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		
Holds a Bachelors or Masters Degree in an applicable Engineering discipline (e.g. Chemical or Process Engineering) or equivalent practical experience in a similar role	☒	☐
Chartered Engineer Status (i.e. typically 4 years Post Graduate in a Professional Institute Approved Structured Programme, Peer Reviewed Report, fully attested training and experience diary followed by Interview with Chartered Institute)	☐	☒
Member of relevant professional body e.g. IChemE or ISPE	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
• Can demonstrate practical experience of the operation, commissioning, troubleshooting and/or validation of equipment, utilities and facilities used in the manufacture of pharmaceutical products	☒	☐
• Possesses broad technical knowledge, including a thorough grasp of the underlying engineering principles and regulatory framework, related to the processes, equipment and technologies used in the manufacture of pharmaceutical products under cGMP	☒	☐
• 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	☒	☐
• Has previous practical experience of leading Root Cause investigations, either solely or as part of an investigation team and implementing Corrective and Preventative actions	☐	☒
• Experience in the delivery of Capital Projects within a pharmaceutical manufacturing environment, as Project Manager and/or in a technical engineering role	☐	☒
• Has previous knowledge or experience of the practical application of process improvement or lean manufacturing tools and methodologies (e.g. Six Sigma)	☐	☒
• Experience as a technical SME during external (e.g. FDA and MHRA) Regulatory inspections and internal QA audits.	☐	☒
• Specialist knowledge of Aseptic Pharmaceutical GMP Manufacturing processes, associated equipment technologies and design, acquired through post graduate diploma or practical experience	☐	☒

• Specialist knowledge of Biopharmaceutical GMP Manufacturing processes, associated equipment technologies and design, acquired through post graduate diploma or practical experience	☐	☒
Skills and capabilities		
• Possesses a systematic and thorough set of troubleshooting skills. Capable of leading small teams to identify and resolve equipment and system performance issues affecting ongoing manufacture whilst maintaining compliance with cGMP.	☒	☐
• Can perform accurate and clear record keeping in keeping with Good Document Practice	☒	☐
• Technical writing skills suitable for the creation of Engineering reports, Engineering protocols and Engineering design documentation, including design drawings.	☒	☐
• Diplomatic and tactful approach to colleagues. Excellent communication skills as main point of contact for engineering issues to stakeholders	☒	☐
• Excellent organisational skills	☒	☐
• Possess a good level of Computer skills in standard software (Microsoft Office)	☒	☐
• Possess a good level of numeracy	☒	☐
• Demonstrated Project Management skills	☐	☒
• Ability to perform Project Planning using appropriate tools and aids	☐	☒
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:	