Job description

Job title	Process Engineer
Directorate	Engineering
Career Level	Career Level 3
Responsible to	Ian King
Base/location	Porton Down
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd, 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 Vaccine as well as contract manufacturing projects.

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 System technical expert for all Engineering Utilities systems within the GMP Envelope, and is responsible for identification of and managing small projects/initiatives relating to utilities systems and interfacing with the wider Pharmaceutical Engineering group to ensure Utilities systems within the GMP envelope remain compliant with current Good Manufacturing Practice.

Communication and key working relationships

<u>Internal</u>

- Manufacturing
- 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

- To monitor Utilities equipment trend data as provided by the computerised maintenance management system and liaison with the maintenance teams/users, to recommend and manage process improvements/initiatives, and when required prepare justifications for submission within the appropriate capital budget.
- Project Manage small business critical GMP projects as delegated by the Process Engineering Manager in accordance with the PBL GMP Capital Project procedure.
- Deputise for the Process Engineering Manager providing technical guidance and training to the wider Pharmaceutical engineering team and administering business process related tasks through the computerised maintenance management system.
- Represent the Engineering function at BSI, MHRA and FDA audits as subject matter expert for Utilities supported by the Process Engineering Manager.
- To be responsible for the writing, and review of User Requirement specifications, SOP's, and generation of design documentation related to Utilities systems and other equipment within the GMP envelope.
- Review and Approval of Engineering technical regulatory documents as required to support the Engineering function including review and approval of Safety related documents such as pressure systems written schemes of examination.
- Responsible for troubleshooting and liaising with maintenance technicians, engineers and users to establish the root cause, develop and manage appropriate corrective action plans and report through the PBL non conformance system, for failures/performance issues.
- Represent Engineering as Project Engineer and system expert on capital projects.

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			
• Masters Degree in Process or Chemical Engineering with post graduate experience in a plant and/or design engineer role	☒	☐	A, I
• 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)	☐	☒	A, I
• Extensive experience in an Engineering operational and design role in the Pharmaceutical Industry. • Experience of Successfully leading a variety of major specialist engineering initiatives • Effective leadership and project management skills • Experience of Regulatory Audits • Experience in Preparing Detailed GMP Engineering Technical Documentation • Project Management training	☒	☐	A, I
Knowledge and experience Experience as defined by type/level (not length)			
• Extensive Practical, pharmaceutical industry experience of facilities, equipment and GMP Critical Utilities operation, design, commissioning and validation.	☒	☐	A, I
• Experience of current available engineering/equipment technology and its subsequent sizing/selection to support Pharmaceutical Operations	☐	☒	A, I
• Experience of working within a GMP Quality System, in particular, change control, Non Conformance management, CAPA, discrepancy/deviation, and documentation management.	☒	☐	A, I
• Experience of the design, and control of capital project design documentation within a GMP quality systems environment.	☐	☒	A, I

• Experience of project management of capital project delivery within a pharmaceutical manufacturing environment.	☐	☒	A, I
• Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction	☒	☐	A, I
• Experience as an SME of FDA and MHRA Regulatory inspections	☐	☒	A, I
• Specialist knowledge of Biopharmaceutical GMP Manufacturing processes, associated equipment technologies and design, acquired through post graduate diploma or practical experience	☐	☒	A, I
• Specific knowledge of FDA and MHRA regulatory requirements (i.e US 21 Code of Federal Regulations parts 210 and 211; Eudralex Volume 4 part 1 Annexe 1)	☒	☐	A, I
• Working knowledge of pharmaceutical facility design and construction and comprehensive understanding of the underlying engineering principals	☐	☒	A, I
• Evidence of post qualifying and continuing professional development	☒	☐	A, I
• Member of relevant professional body	☒	☐	A, I
Skills and capabilities			
• Accurate and clear record keeping • Wide GMP experience • Specialist knowledge of Utilities System Design Concepts, and solutions 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	☒	☐	A, I
• Demonstrated Project Management skills. • Project Planning • 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:…….....…