Job description

Job title	Compliance Engineer
Division	Engineering
Career Level	3
Responsible to	Process Engineering 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 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 Compliance Engineer is responsible for supporting the Quality Engineer to maintain the compliance of manufacturing operations within PBL with the requirements of the PBL Quality Management system. They perform this task by working within a multidisciplinary Integrated Process Team alongside PBL colleagues drawn from the Engineering, Quality and Production groups. They will be accountable for the performance of the engineering function within the Integrated Process Team against internal Quality System metrics for engineering led activities. The Compliance Engineer will in addition support the Process Engineer and Process Equipment Engineers within the IPT and will lend them assistance with the co-ordination of Engineering activities, the troubleshooting of failures and the delivery of reactive remedial works and process improvements.

Communication and key working relationships

Internal

- Manufacturing
- Quality
- Engineering
- Maintenance and Calibration Technicians

- Safety
- Validation
- HR

External

- Specialist Contractors
- Suppliers
- Consultants
- Regulators

MAIN DUTIES AND RESPONSIBILITIES

- To lead the investigation and root cause analysis determination of deviations within integrated process teams (IPTs) through the PBL non-conformance system
- To initiate and support Process Engineers and Process Equipment Engineers in the completion of continuous improvement actions and CAPA actions
- To support the Quality Engineer, ensure the timely compliance of activities managed by the PBL QMS within agreed timelines
- To support the Process Engineers and Process Equipment Engineers in fault finding following failures or performance issues and to support the coordination of planned and corrective engineering activities such as maintenance and calibration
- To monitor the performance of critical systems supporting manufacturing including HVAC and critical utilities
- To be responsible for the maintenance and update of Standard Operating Procedures relating to Engineering workflows.
- To maintain visual status information relating the Engineering function within the IPTs

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/AS Level qualifications (or an equivalent academic or vocational qualification)	☒	☐
Holds a bachelor's degree (or equivalent e.g. NVQ or Diploma) in a science or engineering based subject or has completed an appropriate Engineering apprenticeship	☐	☒
Hold a qualification or certification to at least a basic level in a Continuous Improvement methodology or toolset (for example holds a Six Sigma Yellow Belt)	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
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 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 knowledge or experience of the practical application of process improvement or lean manufacturing tools and methodologies (e.g. Six Sigma)	☐	☒
Experience as an auditee 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		
Can perform accurate and clear record keeping in keeping with Good Document Practice	☒	☐
Technical writing skills suitable for the creation of Engineering	☒	☐

and Root Cause Analysis reports, Engineering protocols and Engineering procedures.		
Diplomatic and tactful approach to colleagues and good communication skills	☒	☐
Possess a good level of Computer skills in standard software (Microsoft Office)	☒	☐
Possess a good level of numeracy	☒	☐
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:	