

Job description

Job title	Compliance Engineer
Directorate	Engineering
Career Level	Career Level 3
Responsible to	Process Engineering Manager
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 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 work flows.
- To maintain visual status information relating the Engineering function within the ITPs

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			
Holds A/AS Level qualifications (or an equivalent academic or vocational qualification)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I
Holds a Bachelors Degree (or equivalent e.g. NVQ or Diploma) in a science or engineering based subject or has completed an appropriate Engineering apprenticeship	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A, I
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)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A, I
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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I
Experience of working within a GMP Quality System, in particular, change control, Non Conformance management, CAPA, discrepancy/deviation, and documentation management.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I
Experience of dealing with internal customers, negotiating and agreeing work programmes, reporting progress, dealing with issues to ensure delivery and customer satisfaction	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I
Has previous knowledge or experience of the practical application of process improvement or lean manufacturing tools and methodologies (e.g. Six Sigma)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A, I
Experience as an auditee during external (e.g. FDA and MHRA) Regulatory inspections and internal QA audits.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A, I
Specialist knowledge of Aseptic Pharmaceutical GMP Manufacturing processes, associated equipment technologies and design, acquired through post graduate diploma or practical experience	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A, I
Specialist knowledge of Biopharmaceutical GMP Manufacturing processes, associated equipment technologies and design, acquired through post graduate diploma or practical experience	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A, I
Skills and capabilities			
Can perform accurate and clear record keeping in keeping with Good Document Practice	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I
Technical writing skills suitable for the creation of Engineering and Root Cause Analysis reports, Engineering protocols and Engineering procedures.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I

Diplomatic and tactful approach to colleagues and good communication skills	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I
Possess a good level of Computer skills in standard software (Microsoft Office)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A, I
Possess a good level of numeracy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	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	<input checked="" type="checkbox"/>		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:.....