

Job description

Job title	Assistant Compliance Engineer
Division	Engineering
Career Level	5
Responsible to	Quality Engineer

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 successful applicant will be joining the Engineering division, which is responsible for the 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 Assistant Compliance Engineer will principally be responsible for the sampling of Critical Utilities such as Clean Steam, Water for Injection and Purified Water within Engineering-controlled service areas of the PPC and Immuno facilities. This is an important compliance function which supports the manufacture of PBL products by providing assurance that critical water and steam systems remain in specification. This includes escorting the monthly private water regulations sampling.

This role will require the Assistant Compliance Engineer to access and collect water samples for subsequent analysis in QC laboratories from various locations within Engineering service areas across the PBL site. This will require working in compliance to PBL Standard Operating Procedures and Safety Risk Assessments.

The secondary responsibilities of the Assistant Compliance Engineer will be responsible for maintaining and archiving a library of Engineering O & M (Operation and Maintenance) manuals. This would include providing a trace of which Engineers have booked out copies of the manuals.

The Assistant Compliance Engineer role will include the opportunity to be involved with further compliance related activities including tasks such as gathering and collating compliance data

in support of Engineering group Quality KPIs, performing routine compliance checks on critical utilities and backing up electronic systems such as the Facility Monitoring Systems.

Communication and key working relationships

Internal

- Engineering
- Quality Assurance
- Quality Control
- Safety
- Validation
- HR

External

- Specialist contractors

MAIN DUTIES AND RESPONSIBILITIES

- To routinely perform and document the aseptic sampling of critical utilities including, Purified Water, Water for Injection and Clean steam, within the plant rooms of two manufacturing facilities. To ensure utility compliance for manufacturing of pharmaceutical products.
- To supervise third party water samplers assuring that the samples have been collected correctly and PBL procedures are adhered to.
- To escalate any sampling compliance issues to the Compliance and Quality Engineers, ensuring that utility equipment can be maintained.
- To archive and maintain a library of operations and maintenance manuals for the Engineering department.
- To provide backup support to the Compliance Engineers and Quality Engineer

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 (E²)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	<input checked="" type="checkbox"/>	
A good standard of written and spoken English Language	<input checked="" type="checkbox"/>	
Qualification		
GCSE English, Mathematics and Science or equivalent qualification	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Educated to minimum of NVQ 2 level in a scientific subject or equivalent level of qualification or significant equivalent previous proven experience	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Knowledge and experience Experience as defined by type/level (not length)		
Worked within a regulated manufacturing environment	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Worked within a quality system e.g. cGMP/ISO	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Previous experience of working with computerized data systems	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Understanding of aseptic technique	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Previous experience of working in accordance with written instructions, standard operating instructions or safety risk assessments	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Skills and capabilities		
Can perform accurate and clear record keeping in line with Good Document Practice (or equivalent/similar standard)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Flexible approach to work	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Be proactive and able to work on own initiative, organizing and prioritizing own workload to set deadlines	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Must possess a basic level of computer literacy including familiarity with standard Microsoft Office software such as Word, Excel and Outlook.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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"/>	

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	