

## Job description

<b>Job title</b>	Quality Compliance Officer
<b>Directorate</b>	Quality
<b>Career Level</b>	3
<b>Responsible to</b>	Product Quality Manager

### INTRODUCTION

Porton Biopharma Ltd, Porton Down has approximately 400 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The Company carries out the manufacture of Erwinase<sup>®</sup> and Anthrax Vaccine as well as contract manufacturing projects.

The position is based in the QA Compliance Team where a number of key activities are performed.

These include the management of the non-conformance and CAPA systems to support the manufacturing and testing of pharmaceutical products to GMP, the management of change control and risk management systems, the management for the internal and supplier audit management programmes, the management of the product review process the management of QA environmental compliance and the provision of QA oversight of manufacturing and testing activities.

### JOB SUMMARY

The post holder will support an In Process Team (IPT) assigned to a particular manufacturing process. The post holder will support the team by performing all duties associated with the release of pharmaceutical products in a compliant and timely fashion.

### Communication and key working relationships

#### Internal

- Development and Production, Quality, Safety, Validation, Primary Engineering Contractor, Facilities Management, Engineering and Research.

#### External

- Commercial customers, consultants, regulatory authorities, suppliers, testing laboratories.

## MAIN DUTIES AND RESPONSIBILITIES

1. To support the co-ordination and planning of the IPT workload, ensuring Quality matters are considered and acted upon in a compliant fashion.
2. To actively participate in Quality investigations, change controls and risk assessments associated with the IPT to ensure Quality considerations are taken into account.
3. To facilitate and lead structured investigations using recognised models such as “5 Whys” and “FMEA”.
4. To perform the review and approval of a number of key documents associated to the IPT including but not limited to: validation, SOPs, change controls, investigations, risk assessments, pre manufacturing checks, facility release.
5. To perform review of batch manufacturing records and release relevant material for the next stage of manufacture.
6. To provide appropriate QA oversight of manufacturing and testing processes within the IPT to support the business (including occasional out of hours).
7. To participate in the data gathering/review for the quarterly trending reports and annual PQR for the related stage of manufacture
8. To provide training and coaching to more junior members of the team and to staff from other departments in order to promote a quality culture.
9. To promote and enforce data integrity compliance within the IPT and across PBL.
10. If relevant to the specific IPT, to provide review and approval support to EM investigations, smoke visualisation studies, product complaint investigations.
11. To liaise with customers, consultants and contractors as required.
12. To escalate relevant issues to line management and/or to the QP.
13. To provide KPI reports measuring the performance of the team.
14. To undertake relevant training.
15. To undertake work in accordance with the PBL Health and Safety policies and procedures and to work within any Quality Systems that are applicable to the site.
16. To comply with PBL policies and procedures and core values and behaviours.

### 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

	Essential	Desirable
<b>Eligibility</b>		
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"/>	
<b>Qualification</b>		
Educated to degree level or HND in relevant subject (e.g. Microbiology, or a related subject) or a demonstrable equivalent level of experience of working at a similar level in specialist area	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Membership of IQA, RSC, IOB or equivalent	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Knowledge and experience</b> Experience as defined by type/level (not length)		
Experience in operating quality systems in a GMP environment with proven evidence of encountering a wide range of situations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Experience of preparing and providing accurate documents and reports in a timely fashion.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Practical experience in GMP Biopharmaceutical manufacture, testing or engineering, with proven evidence of encountering a wide range of situations.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Working knowledge of ISO, GLP, GCP and other GxPs.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Extensive experience of using an eQMS system in a QA environment.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Experience in training/troubleshooting small groups of staff.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Skills and capabilities</b>		
Excellent proven communication, tenacity and interpersonal skills.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ability to work with a minimum of supervision and to prioritise own work	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Strong customer focus	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Excellent personal effectiveness	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Excellent technical writing	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Equality and diversity</b>		
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:	