Job description

Job title	Junior Compliance Officer
Directorate	Quality
Pay band	Band 4
Responsible to	Product Quality Manager
Base/location	Porton
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma, 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 Precipitate 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 QA in the In-Process Team (IPT) assigned to a particular manufacturing process. The postholder 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 assist in Quality investigations, change controls and risk assessments associated with the IPT to ensure Quality considerations are taken into account.

4. To support 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 assist review of batch manufacturing records and release relevant material for the next stage of manufacture.

6. To assist appropriate QA oversight of manufacturing and testing processes within the IPT to support the business (including occasional out of hours).

7. To assist in the data gathering/review for the quarterly trending reports and annual PQR

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.

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

Description	Essential	Desirable	Assessment
Qualification			
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	√		C
Membership of IQA, RSC, IOB or equivalent		√	C
Knowledge and experience Experience as defined by type/level (not length)			
Experience in operating quality system(s) in a GMP QA environment with proven evidence of encountering a wide range situations.	√		A, I
Experience of preparing and providing accurate documents and reports in a timely fashion.	√		A, I
Practical experience in GMP Biopharmaceutical manufacture, testing or engineering, with proven evidence of encountering a wide range of situations.		√	A, I
Working knowledge of ISO, GLP, GCP and other GxPs.	√		A, I
Extensive experience of using an eQMS system in a QA environment.		√	A, I
Experience in training/troubleshooting small groups of staff.		√	A, I
Skills and capabilities			
Excellent proven communication, tenacity and interpersonal skills.	√		A, I
Ability to work with a minimum of supervision and to prioritise own work	√		A, I

Strong customer focus	√		A, I
Excellent personal effectiveness	√		A, I
Excellent technical writing	√		
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:…….....…