Job description

Job title	Compliance Officer
Directorate	Quality
Career Level	3
Responsible to	Compliance Officer
Base/location	Porton Down
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma, Porton Down has approximately 350 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 and Anthrax 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 batch release system, the non-conformance and CAPA systems to support the manufacturing and testing of pharmaceutical products to GMP, the management of the internal and supplier audit management programmes, the management of QA environmental compliance and the provision of QA oversight of manufacturing and testing facilities.

JOB SUMMARY

The post holder will support the product quality manager to provide QA oversight confirming that activities in manufacturing and testing areas are performed to procedures, to GMP requirements, with the appropriate data integrity compliance. The post holder will provide advice to operational areas and may be required to coach staff as required.

The post holder will assist with the review and management of CAPA issues; change control, risk assessments, failure and deviation investigations, follow up of non-conformances, attend project meetings, reviewing performance of facility suppliers and training of staff. Administrative support for the team, advising and assisting in specific projects and / or operational area is also a requirement of the role.

The post holder will support non-conformance investigations linked to all aspects of manufacturing and testing of Pharmaceutical manufacture. The post holder will review the investigations and provide advice to ensure resolution of the non-conformances

and the implementation of timely CAPAs. The post holder will provide training/advice to staff for the use of the electronic management system.

The post holder will need to be able to work weekends where required to support the business needs.

Communication and key working relationships

Internal

- Development & Production,
- Quality,
- Safety,
- Validation,
- Primary contractor,
- Facilities Management,
- Engineering,
- Research,
- Qualified person(s),
- senior / project managers,
- customers,
- production operators and technicians.

External

- Regulatory inspectors,
- External contractors,
- Customers,
- Auditors.

MAIN DUTIES AND RESPONSIBILITIES

- To investigate Quality compliance issues within GMP areas and prepare associated reports.
- To negotiate corrective and preventive actions necessary to achieve compliance.
- To support the continuous improvement of procedures related to the non-conformance and CAPA system.
- To provide training and troubleshooting support to relevant staff for the operation of the electronic non-conformance system.
- To participate in staff GMP training.
- To provide technical and compliance advice (Quality oversight) to project teams.
- To keep up to date with regulatory requirements and technical advances.
- In line with overall responsibilities, to perform other tasks assigned or objectives set by Line Management.
- To undertake work in accordance with the HPA's Health and Safety policies and procedures and to work within any Quality Systems that are applicable to the site.
- To comply with all Porton Biopharma policies and procedures.

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 your line manager.

The job description and person specification may be reviewed on an ongoing basis in accordance with the changing needs of the PBL.

It should be noted that the work of the division is of a confidential nature and must not be communicated to other persons except where required for authorized purposes.

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	√		A, C
Membership of IQA, RSC, IOB or equivalent		√	A,
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
Proven experience in operating a GMP non-conformance system in a QA environment in a wide range of situations.	√		A, I
Experience of preparing and providing accurate documents and reports in a timely fashion.	√		
Practical experience in GMP Biopharmaceutical manufacture, testing or engineering, with proven evidence of encountering a wide range of situations.		√	A, I
Working knowledge of 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 in using electronic systems.		√	
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
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**