Job description

Job title	Senior QC Analyst (Raw Materials)
Division	Quality
Career Level	3
Responsible to	QC First Line Manager (Raw Materials)

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized company 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 Vaccine as well as contract manufacturing projects.

Analytical Quality Control Laboratory

The Analytical Quality Control Laboratory is part of the Development and Manufacturing Group at Porton Down which develops and manufactures biopharmaceutical products according to cGMP requirements. The laboratory is responsible for provision of analytical chemistry services to support quality control testing of products, raw materials and water systems. A stability study programme is also maintained to meet regulatory requirements for marketed products.

JOB SUMMARY

To undertake and supervise chemical and biochemical analyses to support the manufacture of Porton Biopharma's licensed pharmaceutical products; as required by EU Directive 91/356/EEC for GMP compliance. To supervise and schedule work for QC Technologists. To write quality documentation relating to raw materials, water and product testing. To ensure that work performed within the laboratories is carried out in compliance with corporate statutory health and safety requirements.

The post holder will be required to work shift rotation. This rotation includes 2 weeks out of 8 weeks where the shift is 2-10pm and potential weekend working (schedule dependent).

Communication and key working relationships

Internal

- QC Analysts
- QC Senior Analysts
- Laboratory supervisors
- QC First Line Managers
- Analytical Quality Control Manager
- Stability Coordinators
- Quality Assurance personal
- Production Personnel
- Pharmaceutical Stores Personnel

External

- Contract Laboratories
- Participation in audits by external customers and regulatory bodies e.g. MHRA
- Suppliers of instrumentation and chemicals

MAIN DUTIES AND RESPONSIBILITIES

- To deputise for the QC First Line Manager when required.
- To supervise Junior QC Analytical staff.
- To schedule work for QC Analytical staff members to ensure that manufacturing deadlines are met.
- To ensure analysis and recording of QC and stability testing has been performed in compliance with the statutory requirements of cGMP.
- Responsibility for testing raw materials, in process and finished product samples to ensure that they meet the specifications established in the product licence and internal Porton Biopharma specification documents.
- Responsible for writing Standard Operating Procedures and their associated safety risk assessments to ensure that those tasks are performed safely.
- Organise and liaise with external testing laboratories to arrange correct and on time testing to meet production deadlines.
- Maintain an up-to-date awareness of regulatory and scientific developments via courses, meetings and literature.
- Responsible for the verification of analytical raw data and ensure release of results is performed on time as per PBL procedures and released results are accurate and without errors from the QC Analytical department.
- Responsible for writing and reviewing quality records such as Out of Specification (OOS) investigations, non-conformances, CAPAs, quality risk assessments and change controls in line with PBL procedures and current regulatory guidance. Authoring and reviewing supporting information and technical reports associated with quality records. Ensure all quality records are completed on time as per PBL procedures and KPIs are met.
- Perform in depth investigations, lead root cause analysis and write up associated technical investigation reports.
- Monitor compliance within QC Analytical, identify weaknesses and develop strategies to continually improve systems.
- Ensure procedures within QC Analytical are in line with current regulatory regulations and guidance documents.
- Undertake work in accordance with Porton Biopharma’s Code of Safety Practice and Quality Systems.

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 (E^2)

Person specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in the UK	☒	☐
A good standard of written and spoken English Language	☒	☐
Qualification		
Degree in Chemistry/Biochemistry or other suitable degree. (Suitable experience may be considered)	☒	☐
Further degree in Chemistry, Biochemistry or equivalent discipline / membership of a scientific society	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Working Knowledge / Experience of cGMP.	☒	☐
Working Knowledge / Experience of the EP and USP.	☒	☐
Working Knowledge / Experience of ICH requirements.	☒	☐
Previously worked in a laboratory as an analyst following written instructions and comparing analytical results with set specifications.	☒	☐
Knowledge / Experience of Enzyme analysis.	☐	☒
Knowledge / Experience using UV-Vis and FT-IR.	☐	☒
Knowledge / Experience of Waters HPLC systems and associated software or equivalent.	☐	☒
Knowledge / Experience of Gel Electrophoresis.	☐	☒
Experience of the out of specification process and carrying out laboratory investigations.	☒	☐
Experience using standard analytical laboratory equipment such as pH meters, balances, pipettes.	☒	☐
Knowledge / Experience using KF Moisture determination	☐	☒
Knowledge / Experience analysing purified water and water for injection.	☐	☒
Knowledge / Experience analysing pharmaceutical raw materials.	☐	☒
Ability to supervise junior staff and schedule workloads.	☒	☐
Experienced in supervising junior staff and scheduling workloads.	☐	☒
Skills and capabilities		
Good communication skills able to communicate technical issues clearly, both written and verbally with QC and other PBL staff.	☒	☐

Problem solving skills and ability to respond to sudden unexpected demands.	☒	☐
Ability to work on own initiative, organise own workload and prioritise daily work with minimal supervision working to tight and often changing timescales.	☒	☐
Ability to use technical software packages.	☒	☐
Ability to cooperate with and take part in team-based activities.	☒	☐
Good basic computer skills and literacy.	☒	☐
A desire and ability to self-improve and to improve the department.	☒	☐
Able to logically troubleshoot QC analysis.	☒	☐
Able to verify QC data with a good eye for detail.	☒	☐
Able to apply theoretical knowledge to practical situations.	☒	☐
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	☒	☐

Job description agreed with the post holder:

Employee Name:	Date:
Employee Signature:	

Manager Name:	Date:
Manager Signature:	