Job description

Job title	Laboratory Manager, QC Analytical Services
Directorate	Quality
Career Level	3
Responsible to	QC Analytical 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® and Anthrax Vaccine as well as contract manufacturing projects.

Analytical Quality Control Laboratory

The Analytical Quality Control Laboratory is responsible for provision of analytical chemistry services to support quality control testing of Biopharmaceutical products, raw materials and water systems. A stability study programme is also maintained to meet regulatory requirements for marketed products.

JOB SUMMARY

To lead and manage a specialist GMP analytical chemistry/biochemistry laboratory to provide compliant testing of licensed pharmaceutical products.

Communication and key working relationships

Internal

- Analytical QC Manager
- Biological Services Manager
- Stability Manager
- Director of Quality
- Head of Validation Services
- Analytical QC team: - Senior Analysts, Analysts, Technicians
- Director of Production
- Production team
- QPs
- QA Documentation team, non-conformance team, batch release team

External

- Contract test laboratories
- Customers
- Suppliers

MAIN DUTIES AND RESPONSIBILITIES

- To operate the QC Analytical Services Laboratory in compliance with Porton Biopharma's safety policy and cGMP.
- To manage and lead the QC Analytical Services Laboratory and to meet manufacturing deadlines.
- Responsible for staff recruitment, appraisals and management to 'Policies and Procedures' documents. Planning of staff work schedules, resource management and costing work programmes.
- Utilising technical skills to validate specialised chemical and biochemical tests procedures to internationally recognised regulatory guidelines. Conduct problem solving investigations to resolve issues affecting Pharmaceutical manufacture.
- Train staff within the QC Analytical Services Department in laboratory techniques and Quality Management Systems to GMP requirements. Assist staff within QC Analytical Services Department with their ongoing development to aid their career and personal progression.
- Work with project teams and represent QC on these to contribute to the success of these business centres by delivering the required Analytical knowledge and services.
- Play a lead role with both internal and external customers. Present the department and its operation to Regulatory Inspectors representing their respective national bodies.
- Maintain an up to date awareness of regulatory and scientific developments via approved training courses and meetings that will contribute to the efficiency and effectiveness of laboratory working practices and aid personal development.
- To ensure that clinical pharmaceutical products are tested from raw materials and in-process samples to finished products to demonstrate that they meet the specification prior to each batch release for administration to patients.
- Ensure the stability program is successfully executed.
- Maintain a programme of constant improvement.
- Expenditure to financial limits.
- Sign off authority for Pharmaceutical batch release tests
- Review and approval of SOPs, Protocols and Risk Assessments.
- Host audits both from internal and external parties
- Write and review OOS investigations and deviation reports.

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
Eligibility		
Current, valid Right to Work in the UK	☒	☐
A good standard of written and spoken English Language	☒	☐
Qualification		
Degree or equivalent in Chemistry, Biochemistry or related discipline	☒	☐
Further degree in Chemistry, Biochemistry or related discipline	☐	☒
Professional membership of a relevant society e.g. Royal Society of Chemistry	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Extensive experience in a relevant industry Significant experience of working to GMP or other similar quality standard.	☒	☐
Extensive practical knowledge of a broad range of analytical and/or biochemical techniques within a laboratory environment Significant experience of laboratory safety Significant management experience Significant experience of writing/reviewing controlled documents	☒	☐
Knowledge of other discipline (Biochemistry or Chemistry) Validation of analytical methods and stability studies to ICH Q1and Q2 Knowledge of ICH Q3, Q5, Q6 & Q10	☒	☐
Experience of hosting regulatory audits Experience of continuous improvement	☒	☐
Experience in communications and stakeholder management	☒	☐
Skills and capabilities		
Clear communicator with excellent writing, report writing and presentation skills; capable of constructing and delivering clear ideas and concepts concisely and accurately for diverse audiences	☒	☐
Evidence of success in efficient and effective project and programme management	☐	☒
Skills for communication on complex matters and difficult situations, requiring persuasion and influence. Ability to manage a large team in an effective manner, prioritise workload and demonstrate progress.	☒	☐

Ability to analyse and interpret information, pre-empt and evaluate issues, and recommend an appropriate course of action to address the issues including statistical analysis and trending. Problem solving skills and the ability to respond to sudden unexpected demands. Experience of performing root cause analysis and writing compliance documentation. Experience using Quality Management Systems in the Pharmaceutical industry.	☒	☐
Extensive experience of developing analytical methods, method transfer and validation.	☐	☒
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:	

Manger Name:	Date:
Manager Signature:	