Job description

Job title	Analytical Quality Control Manager
Directorate	Quality
Career Level	2
Responsible to	Head of Quality Control

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.

The Quality Control section provides analytical chemistry, biological testing, environmental monitoring and stability services to support production operations, quality control testing of licensed pharmaceutical products, raw materials and water systems.

JOB SUMMARY

To lead and manage a team engaged Analytical chemistry testing in line with regulatory requirements, safety standards and budget constraints. To ensure that changes in worldwide pharmaceutical regulations are recognized and incorporated into QC working practices.

Communication and key working relationships

Internal

- Head of Quality Control
- Director of Quality
- Production Managers
- Biological Services QC Manager
- Qualified Person(s)
- Validation Manager
- Analytical Method Development Manager
- Regulatory Affairs
- Project Managers
- Capital Projects

External

- MHRA (Medicines and Healthcare Regulatory Agency)
- Department of Health (DH)
- Department for Environment, Food and Rural Affairs (DEFRA)
- National Institute for Biological Standards and Control (NIBSC)
- Commercial customers
- Food and Drug Administration (FDA)
- Any other regulators as required

MAIN DUTIES AND RESPONSIBILITIES

- To ensure that all testing, including stability testing, is carried out with appropriately developed, validated and approved methods.
- To ensure that facilities are maintained to meet all necessary operational standards and regulations.
- Utilising input from relevant functions, operational project and production management take all decisions relating to the routine operation of the facility.
- To recruit staff and to plan staff development succession planning to meet current and future needs of the process and production.
- To ensure sufficiently trained staff are in place to carry out the testing and supervision of the testing, procedures and equipment.
- To lead the training, management, appraisal and mentoring of staff to ensure performance, safety and training standards are achieved.
- To coach and mentor members of the Analytical Chemistry testing group and ensure them to meet work objectives and targets.
- To review and implement an organisation structure and work patterns fit to meet the needs of process and production and where necessary propose and implement change.
- To act as the lead expert on analytical methodology and ensure that all laboratory practices, methods and reporting procedures are compliant with pharmacopeial and international guidelines and applicable ISO standards.
- To ensure that all processes and procedures are documented and current for operation of the facility.
- To monitor performance and capacity of analytical test equipment and via contribution to the Pharmaceutical Operations budgets, recommend and provide written justification for new investment.
- To maintain knowledge of current standards and working practices required for analytical testing of biopharmaceutical product.
- To be conversant with current safety legislation and ensure all staff have appropriate training and are compliant with all Health and Safety guidelines.
- To lead regular review of safety standards for the QC Laboratories and related equipment.

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		
Educated to degree level in a relevant life science subject or equivalent level qualification or significant experience of working at a similar level in specialist area.	☒	☐
Post graduate degree in management studies or equivalent.	☐	☒
Knowledge and experience Experience as defined by type/level (not length)		
Substantial knowledge and understanding of MHRA and FDA regulatory requirements in relation to QC	☒	☐
Extensive management experience of pharmaceutical QC laboratories.	☒	☐
Experience of in-process and final product QC testing of biopharmaceutical products.	☒	☐
Experience of analytical method development and validation in line with ICH guidelines	☒	☐
Substantial experience of working within a GMP quality system	☒	☐
Extensive knowledge of specialist areas, acquired through post graduate diploma or equivalent experience or training plus further specialist knowledge or experience to master's level equivalent.	☐	☒
Evidence of post qualifying and continuing professional development	☐	☒
Member of relevant professional body	☐	☒
Skills and capabilities		
Communication Skills		
Must be able to provide and receive highly complex, sensitive or contentious information, negotiate with senior stakeholders on difficult and controversial issues, and present complex and sensitive information to a large and influential groups.	☒	☐
Ability to negotiate on difficult and controversial issues including performance and change.	☒	☐
Analytical Skills		
Problem solving skills and ability to respond to sudden or unexpected demands.	☒	☐
Ability to analyse complex facts and situations and develop	☒	☐

a range of options.		
Takes decisions on difficult and contentious issues where there may be a number of courses of action.	☒	☐
Strategic thinking, ability to anticipate and resolve problems before they arise.	☒	☐
Planning Skills		
Demonstrate capability to plan over short, medium and long term timeframes and adjust plans and resource requirements accordingly.	☒	☐
Compressive experience of project principles, techniques and tools, such as Prince 2 and Managing Successful Projects.	☐	☒
Management Skills		
Must be able to prioritise own work effectively and be able to direct activities of others. Experience of managing and motivating a team and reviewing performance of an individual.	☒	☐
Autonomy/Freedom to Act		
Must be able to use initiative to decide relevant actions and make recommendations to sponsor/manager with the aim of improving deliverables and compliance to policies.	☒	☐
Ability to make decisions autonomously, when required, on difficult issues, working to tight and often changing timescales.	☒	☐
Experience of identifying and interpreting companywide policies	☒	☐
Experience of researching best practice (globally, private and public sector), interpreting its relevance and process/practices which could be implemented successfully.	☒	☐
Financial and Physical Resource Management Experience		
Previously involved in budget. Involved in budget setting and working knowledge of financial processes.	☒	☐
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:	