Job description

Job title	QC Technologist (Analytical)
Directorate	Quality
Career Level	4
Responsible to	QC Analytical Laboratory Manager
Base/location	Porton
Hours/sessions per week	37.5
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd, 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 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 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 write quality documentation relating to raw materials, water and product testing.

Communication and key working relationships

Internal

- QC Laboratory analysts
- Laboratory supervisors
- Laboratory Manager

- Analytical Quality Control Manager
- Quality Assurance personal
- Production personnel
- Pharm stores
- Validation
- Development

External

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

MAIN DUTIES AND RESPONSIBILITIES

- To ensure analysis and recording of QC and stability testing is performed in compliance with the statutory requirements of cGMP.
- Responsibility for testing 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 risk assessments to ensure that those tasks are performed safely and other quality documents e.g. change controls, validation reports, non-conformances and CAPAs where appropriate.
- Organise and liaise with external testing laboratories to arrange correct and on time testing to meet production deadlines or suppliers of equipment or chemicals.
- Organise and liaise with internal departments such as validation, pharmaceutical stores and QA where required.
- Maintain an up-to-date awareness of regulatory and scientific developments via courses, meetings and literature.
- Undertake work in accordance with Porton Biopharma's Code of Safety Practice and Quality Systems.
- Maintain training records.
- Cleaning of laboratories.
- Maintenance and calibration of 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.

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).

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
Eligibility			
Current, valid Right to Work in the UK	☒	☐	A/I
Qualification			
Degree in Chemistry/Biochemistry or other suitable degree. Suitable experience may be considered as suitable	☒	☐	AIC
Higher degree in Chemistry or Biochemistry	☐	☒	AIC
Knowledge and experience Experience as defined by type/level (not length)			
Working knowledge or experience of cGMP	☒	☐	AI
Working knowledge or experience of the EP and USP	☐	☒	AI
Working knowledge or experience of ICH requirements	☒	☐	AI
Previously worked in a similar position as a bench analyst following written instructions and comparing analytical results with set specifications	☒	☐	AI
Knowledge or experience of HPLC analysis	☐	☒	AI
Basic experience of the out of specification process and carrying out laboratory investigations.	☐	☒	AI
Experience using standard analytical laboratory equipment such as pH meters, balances, pipettes	☒	☐	AI
Knowledge or experience using UV-Vis	☐	☒	AI
Knowledge or experience performing SDS-Page	☐	☒	AI
Skills and capabilities			
Good communication skills able to communicate technical issues to Supervisors and understand technical instructions	☒	☐	AI
Fluent in written and spoken English	☒	☐	AI
Problem solving skills and ability to respond to sudden unexpected demands	☒	☐	AI
Ability to work on own initiative, organise own workload and prioritise daily work with minimal supervision working to tight and often changing timescales	☒	☐	AI
Ability to use technical software packages	☒	☐	AI
Ability to cooperate with and take part in team based activities	☒	☐	AI
Good basic computer skills and literacy	☒	☐	AI
A desire and ability to self-improve and to improve the department	☒	☐	AI
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	✓		I

relation to management systems			
***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:…….....…