Job description

Job title	Senior QC Technologist – Method Specialist
Directorate	Quality
Career Level	4
Responsible to	QC Analytical Laboratory Manager
Base/location	Porton Down
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.

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 manage and perform the transfer/validation of analytical methods from Development into a GMP environment in QC Analytical Services. The role involves all activities involved in transferring analytical methods from Development to QC Analytical Services including, writing transfer/validation protocols and SOPs, executing protocols in the laboratory, writing up the associated transfer/validation reports, and training existing members of staff in transferred methods. Reviewing existing methods for compliance and on-going performance is in essential part of this role along with investigations. This role is required to support in-process testing.

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
- Production team
- QPs
- QA Documentation team, non-conformance team, batch release team
- Development team

External

- Contract test laboratories
- Customers
- Suppliers
- Regulatory Inspectors

MAIN DUTIES AND RESPONSIBILITIES

- 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.
- Use technical expertise to be trained in and become a subject matter expert in analytical methods.
- Manage all activities involved in transferring analytical methods from Development to QC Analytical Services including running analytical methods, writing transfer/validation protocols, executing protocols in the laboratory, writing up the associated transfer/validation reports.
- Perform release and stability testing of transferred methods where required.
- Train out analytical methods within a GMP environment.
- 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.
- 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.
- Authorship and review of SOPs, Protocols and Risk Assessments.
- Involvement in audits both from internal and external parties
- Write and review discrepancies, OOS investigations and deviation reports.
- Review existing analytical methods for compliance and on-going performance and initiate continuous improvement activities.
- Perform and review in-process analysis.

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

Description	Essential	Desirable	Assessment
Eligibility			
Right to work in the UK.	☒	☐	A/I
Fluent in English.	☒	☐	A/I
Qualification			
Degree or equivalent in Chemistry, Biochemistry or related discipline.	☒	☐	A/I/C
Further degree in Chemistry, Biochemistry or related discipline.	☐	☒	A/I/C
Professional membership of a relevant society e.g. Royal Society of Chemistry.	☐	☒	A/I/C
Knowledge and experience Experience as defined by type/level (not length)			
Experience of method transfer and validation in a GMP environment to the relevant regulatory guidance (ICH, MHRA, FDA).	☒	☐	A/I
Extensive practical knowledge of a broad range of analytical and/or biochemical techniques within a laboratory environment.	☒	☐	A/I
Awareness and experience of laboratory safety	☒	☐	A/I
Evidence of success in efficient and effective project and programme management.	☐	☒	A/I
Significant experience of authoring/reviewing protocols, reports, SOPs and other relevant documents.	☒	☐	A/I
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.	☒	☐	A/I
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.	☒	☐	A/I
Problem solving skills and the ability to respond to sudden unexpected demands. Experience of performing root cause analysis and writing compliance documentation.	☒	☐	A/I
Experience using Quality Management Systems in the Pharmaceutical industry.	☐	☐	A/I

Ability to use statistical packages such as Minitab to evaluate and interpret results.	☐	☒	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**

Job description agreed with the post holder:

Employee signature: ……. Date:……

Print name:…….....

Manager’s signature:…….. Date:……

Print name:…….....…