Job description

Job title	Mass Spectroscopy Specialist
Directorate	Development Group
Career Level	Level 2
Responsible to	Characterization Lead, Development Group
Base/location	Porton, Main Site
Hours/sessions per week	37.5 hrs per week
Job type	Permanent

INTRODUCTION

Porton Biopharma Ltd (PBL), Porton Down has approximately 300 staff, performing a range of production, quality and development roles within pharmaceutical production, process and analytical development, quality control and quality assurance. The department carries out the manufacture of Erwinase® and Anthrax Vaccine as well as contract manufacturing projects.

The Development Group is a development and technology transfer group playing a key role in the translational research activities of the site. Its role is to develop manufacturing processes and associated analytical methods for use in the cGMP production of bio-therapeutics and healthcare interventions including vaccines. Projects may comprise the development of research designs and/or the improvement of existing commercial processes. The department is organized into 4 core teams with responsibility for product development, *in vitro* culture processes, downstream purification processes and analytical method development. Within the analytical method development team, a number of separation technologies involving LC equipment and electrophoretic means are employed in addition to mass spectrometry.

JOB SUMMARY

The post holder will work with the analytical method development team of PBL in identification, process improvement, and characterization studies which are business-critical and associated with the company's product line. PBL currently manufactures a licensed protein therapeutic for the treatment of childhood acute lymphoblastic leukemia (ALL) and an Anthrax vaccine. Mass spectral analyses play a fundamental role in the characterization and process improvement efforts associated with these products. They include, but are not restricted to:

- Establishing host cell protein (HCP) clearance profile through construction and interrogation of protein spectral libraries.
- Assessment of post-translational modifications in protein bio-therapeutics.
- Absolute quantification of specific antigens expressed in culture related to vaccine efficacy, using multiple reaction monitoring (MRM) and isotope dilution-mass spectroscopic (ID-MS) approaches.

Mass spectral support of the company's pipeline projects is also anticipated. The successful candidate will conduct investigatory analyses as needed using a triple time-of flight (TOF), AB Sciex 6600 high resolution mass spectrometer, via parallel reaction monitoring (PRM), data dependent acquisition (DDA) and data independent acquisition (DIA) approaches. They will be responsible for novel MS method development, including associated tandem LC methods, for targeted analyses as well as proteomics-based investigations in DIA mode. They will also be responsible for developing LC-MS methods for characterization of bio-therapeutic protein post-translational modifications as required by regulatory authorities. The successful candidate will be expected to compile relevant protocols and reports, perform appropriate statistical data analyses, and provide written and oral presentations of their results. The successful candidate will also be expected to be self-motivated to undergo any necessary training in relevant software and related applications to support contemporary approaches to MS investigations. Additional responsibilities for this role will extend to training junior members of the team as needed to support related characterization studies, general troubleshooting, and assisting where required with related duties in the laboratory.

Communication and key working relationships

Internal

- Direct reports and wider Development staff at all levels including other Functional Leads, Specialists and Managing Director.
- Functional Managers, Unit Managers and Project Managers
- Staff within Quality and associated departments.

External

- Customers and associated contacts.
- Sub-contracted scientific organisations and service providers.
- National and international scientific experts; academic institutions and students
- Regulatory Authorities.]

MAIN DUTIES AND RESPONSIBILITIES

PBL currently manufactures a licensed protein therapeutic for the treatment of childhood acute lymphoblastic leukemia (ALL) and an Anthrax vaccine. Mass spectral analyses play a fundamental role in the characterization and process improvement efforts associated with these products. They include, but are not restricted to:

- Establishing host cell protein (HCP) clearance profile through construction and interrogation of protein spectral libraries.
- Assessment of post-translational modifications in protein bio-therapeutics.
- Absolute quantification of specific antigens expressed in culture related to vaccine efficacy, using MRM and ID-MS approaches.

- Mass spectral support of the company's pipeline projects is also anticipated. The successful candidate will conduct investigatory analyses as needed using a triple TOF, AB Sciex 6600 high resolution mass spectrometer, via PRM, DDA and DIA approaches. They will be responsible for:
- Novel MS method development, including associated tandem LC methods, for targeted analyses as well as proteomics-based investigations in DIA mode.

They will also be responsible for developing LC-MS methods for characterization of bio-therapeutic protein post-translational modifications as required by regulatory authorities. The successful candidate will be expected to compile relevant protocols and reports, perform appropriate statistical data analyses, and provide written and oral presentations of their results. They will also:

- Take responsibility for liaising with customers including teleconferences, project reports, presentations and on-site/off-site visits.
- Establish and maintain collaborations within and outside of PBL towards our scientific development and to further our products.
- Contribute to or take the lead on publications in national and international journals.
- Provide assistance as required to regulatory enquiries and inspection findings.
- Provide assistance as required to business enquiries.
- Undertake all work in accordance with PBL-wide and local quality systems, ensuring that data generated are valid and fit for purpose.
- Undertake all work in accordance with PBL risk management and safety policies and procedures.
- Deputize, when required, for the Characterization Lead.
- Take responsibility for the supervision and training of junior staff where appropriate.
- Perform any other duties required by the line manager commensurate with grade.
- Comply with all PBL policies and procedures.

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
Qualification			
Degree in Chemistry/Biochemistry or relevant scientific discipline - BS or equivalent	☒	☐	A, C
MSc or PhD in Chemistry or relevant scientific discipline	☐	☒	A, C
Knowledge and experience Experience as defined by type/level (not length)			
• Expert knowledge in the development of a range of LC-MS methods for analysis of biopharmaceutical products • Expert knowledge in the development of MS/MS methods used in identifying and quantitating peptide precursors • Experience in use of high resolution MS in proteomics investigations, both targeted and untargeted • Experience in identifying protein post-translational modifications • Experience in use of contemporary methods to build and interrogate protein and peptide spectral libraries • Experience in statistical analyses of data packages • Experience in dealing with external customers	☒	☐	A, I
• Experience in protein/peptide quantitation in complex matrices through isotope dilution mass spectroscopy (ID-MS) methods • Recognised in own field through publication record • Experience in supporting biopharmaceutical product development	☐	☒	A, I
Skills and capabilities			
• Ability to design, draft and critically review scientific papers, study protocols, reports, operating procedures and codes of practice. • Good oral and written communication skills • Good organisational skills, meticulous and able to meet deadlines • Good statistical analysis skills applicable to the role • Ability to evaluate risks, and build safe working procedures • Self-motivating and flexible	☒	☐	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:…….....…