

Job description

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|-----------------------|------------------------------------|
| Job title | Analytical Method Development Lead |
| Division | Development |
| Career Level | 3 |
| Responsible to | Head of Analytical |

INTRODUCTION

Porton Biopharma Ltd, Porton Down is a medium sized life-science company performing a range development and manufacturing roles for biopharmaceuticals. This also includes all associated support functions from logistics through to engineering, quality control / quality assurance, regulatory affairs and management. The Company manufactures two licensed products, Erwinase[®] and the UK's Anthrax Vaccine as well as providing R&D services for product development.

The Development Group undertakes development and technology transfer activities and plays a key role in the translational research activities of PBL. The role of the group is to develop manufacturing processes and associated analytical methods for use in the cGMP production of biotherapeutics and healthcare interventions. The group is organised into 4 core teams responsible for new product development, in-vitro fermentation processes, downstream processes and analytical method development

JOB SUMMARY

The post holder will lead and co-ordinate the activities of a team of analytical scientists to undertake analytical method development projects. They will also be required to act as a scientific lead for a range of analytical methods including chromatography and biological tests such as UV/VIS spectrometry. The post holder will also ensure that the team complies with Quality and Health & Safety policies, processes and procedures.

The post holder will be expected to ensure the team support routine analytical testing activities undertaken within the group in association with process development, product understanding and during implementation of changes to GMP manufacturing process.

The role requires experience of managing people and multiple projects, designing and executing programs of work, transferring analytical methods, troubleshooting of established test methods, liaising with external laboratories, data integrity of test results and the preparation of technical documentation and user requirement specifications for equipment.

The successful candidate will line manage staff within the team who will be working in a range of functions associated with the wider analytical operational area. Line management will

encompass all associated activities such as recruitment, performance management, supervision and training.

Communication and key working relationships

Internal

- Direct reports and Development group staff at all levels including other functional leads, specialists, department director.
- Functional Managers, Unit Managers and Project Managers
- Staff at all levels within Quality, Manufacturing and associated departments

External

- Customers and associated contractors
- Suppliers
- Sub-contracted scientific organisations and service providers
- Academic institutes
- National and International scientific experts; academic institutions and students
- Regulatory Authorities and Inspectors

MAIN DUTIES AND RESPONSIBILITIES

- To be responsible for line management of staff including scientific management, performance management, supervision and training.
- To support the recruitment of new and replacement positions.
- Ensuring that testing and reporting of results, generated from routine analysis, occur in a timely manner.
- To co-ordinate and liaise with relevant staff across the business to support analytical testing of samples.
- To review and check data to ensure accuracy and compliance to processes and procedures within set deadlines.
- To identify, evaluate, adapt and introduce new analytical technologies where appropriate, providing sound scientific study to ensure such technologies are fit for purpose and cost effective.
- To take responsibility for the analytical development work packages as assigned by the Line Manager: design, initiation, monitoring and implementation.
- Co-ordinate and manage project activities across Development functional groups and Production and where appropriate Research teams.
- Establish collaborations within and outside PBL, as necessary, to benefit the project and or department.
- To ensure good communications within the group on matters such as safety, quality, training, project aims and timelines.
- To assist, as specified by the Line Manger, to regulatory enquiries and inspection findings and to business enquiries.
- To contribute or take the lead on publications in national and international journals.
- To undertake all work in accordance with PBL wide and local quality systems, ensuring that data generated are accurate, valid and fit for purpose.
- Undertake all work in accordance with PBL risk management and safety policies and procedures.
- To comply with PBL policies and procedures.
- Deputise, when required, for the Line Manager.
- Perform any other duties required by the Line Manager commensurate with the grade.
- To work closely with the Process, Analytical Lead, Development Specialist, Project Managers and Business Development Manager in the negotiation and initiation of new studies involving the group.

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.

You should adhere PBL values and behaviors:

- Passion
- Respect
- Integrity
- Diligence
- Excellence in Execution (E²)

Person specification

| | Essential | Desirable |
|---|-------------------------------------|-------------------------------------|
| Eligibility | | |
| Current, valid Right to Work in the UK | <input checked="" type="checkbox"/> | |
| A good standard of written and spoken English Language | <input checked="" type="checkbox"/> | |
| Qualification | | |
| Degree in Biological Science, Chemistry or similar | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| MSc or PhD in Biological Science, Chemistry or similar | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Knowledge and experience Experience as defined by type/level (not length) | | |
| Experience and knowledge in the development of a range of analytical methods used for the analysis of biopharmaceutical products; experience of advanced biochemical techniques through R&D, pre-clinical and/or clinical stages. | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Experience of managing projects and staff in biopharmaceutical development and driving product development programmes through agreed timelines and objectives | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Experience and knowledge of analytical method evaluation and technical transfer procedures. | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Management and Leadership experience. | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Experience of preparing technical documents such as proposals, protocols and reports. | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Presentation of work to internal and external customers. | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Ability to evaluate risks and build safe working procedures. | | |
| Experience in working within a regulated quality system (e.g. ISO 9001, GMP). | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Skills and capabilities | | |
| Supervisory/Management Skills, Team Leadership, Communications both written and verbal, and good Interpersonal skills | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Project Management, good business and strategic sense, planning, prioritising and organizational skills | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Analytical and problem-solving skills & project design skills | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Keen eye for detail and ability to meet deadlines | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Self-motivating, proactive and flexible. | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 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 | <input checked="" type="checkbox"/> | |

Job description agreed with the post holder:

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|---------------------|-------|
| Employee Name: | Date: |
| Employee Signature: | |

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|--------------------|-------|
| Manager Name: | Date: |
| Manager Signature: | |