Job Description
Senior Scientist

Title:	Senior Scientist	**Department:**	Product Development
Reports to:	Team Leader	**Date Prepared:**	October 2022

Broad Function

To lead project work and perform general duties within the relevant laboratory sections of Arecor.

Principal Responsibilities: Product Development

- Provide knowledge of drug product process development, performing scale up studies in the laboratory and supporting CMC team during transfer to CMO sites
- Lead the Identification of appropriate analytical methods for release and stability testing of manufactured products
- Perform analytical method validation and monitoring of method performance
- Provide regular updates on all assigned projects to relevant stakeholders
- Maintain and develop state of the art knowledge applicable to existing and future processes and maintain up-to-date knowledge on guidance surrounding product development

Principal Responsibilities: Management

- Line management of direct reports including setting and monitoring: i) priorities, ii) training, iii) personal development plans and iv) objectives.
- Lead project team meetings and provide expert technical/scientific advice to Arecor stakeholders. Represent the company at external seminars, conferences and supplier visits as required.
- Writing of protocols and reports and develop project work plans including timelines and costs.
- Project management and reporting to all stakeholders, which may include pharma or biotech partners, external alliances, or the Management Team.
- Build strong relationships and trust with stakeholders through delivery of project milestones and the highest level of data integrity. Proactively identify opportunities to improve quality and efficiency of the programs.

Principal Responsibilities: Technical leadership

- Independently lead, design, plan and manage own studies as required to achieve objectives and those of Arecor stakeholders.
- Represent Arecor at project team meetings and provide expert technical advice to stakeholders.

- Foster an environment of continuous improvement and innovation, to challenge established work practices and evaluate and implement efficiency and quality improvements as required and in collaboration with appropriate functional areas.
- Perform routine duties as required in the relevant laboratory section to ensure the timely generation of accurate data and information
- Carry out other reasonable tasks as required by the line manager.

Principal Responsibilities: Quality and Health and Safety

- Champion quality processes for the laboratory on behalf of Product Development, working closely with other quality champions and QA to enable continuous improvements.
- Ensure tasks performed in the laboratory by themselves and direct reports are completed according to the relevant SOP and protocols following ALCOA principles.
- Ensures all direct reports read the appropriate RA and COSHH before performing any task
- Ensure that all project data produced by self and by direct reports is accurately recorded in electronic lab book in a timely manner and appropriately archived, and all data officially reported to stakeholders is QC checked.

The above duties and responsibilities are not an exhaustive list and you may be required to undertake any other reasonable duties compatible with your experience and competencies. This description may be varied from time to time to reflect changing business requirements.

Principal Relationships

- Accountable to line manager.
- Responsible for internal development projects as required.
- Liaise with internal personnel at all levels of the business as required.
- Liaise with external third parties as required.

Education and experience

- A BSc, MSc or PhD in Life Sciences or equivalent
- PhD with 3+ years' experience in a pharmaceutical product development setting / Bachelor's degree + 5+ years' experience in a pharmaceutical product development setting
- Significant experience (2+ years) of working within the pharmaceutical industry performing process development/scale up of drug product formulation.

- Experience of the development, qualification and validation of a range of analytical methodologies suitable for determining the quality, characteristics and stability of biotherapeutics.
- In depth knowledge of analytical methods such as SEC, RP-HPLC, CEX, HPAE, UV, DLS, ELISA etc as required to demonstrate the stability of biotherapeutics.
- cGMP experience and awareness essential including experience of non-conformances, deviations, change control and validation practises.
- Experience of regulatory filling for FDA and EMA advantageous (IND and IMPD preparation)
- Experience of protein characterisation advantageous
- Formulation experience advantageous.
- Line Management experience

Skills and Attributes

- Strong communication, planning, team working and organisational skills
- Competent and organised self-starter with the ability to perform multiple tasks concurrently.
- Able to take responsibility and give direction as required.
- Ability to work closely with others, encourage good team spirit, motivate a multi-skilled team to higher goals and demonstrate initiative as required.
- Ability to mentor and develop junior staff and progress them swiftly into robust independent scientists
- Self-motivated and able to work both individually and within a team
- Methodical, organised with an aptitude for detail.

Issued by: _____ Date: _____

Manager

Accepted by: _____ Date: _____

Job Holder