Job Description
Principal Scientist

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

Broad Function

Lead a scientific team to deliver Arecor projects, targets and timelines on specific areas or disciplines and achieve the company objectives.

Principal Responsibilities: Product Development

- Provide expert knowledge and leadership on drug product process development, performing scale up studies, identifying key critical control parameters to maintain product quality and supporting CMC team during transfer to CMO sites
- Lead the Identification of appropriate analytical methods for release and stability testing of manufactured products.
- Provide other team members guidance on analytical method validation and monitoring of method performance
- Periodically evaluate analytical method SOPs, identifying improvement opportunities where relevant, evaluating validation impact of improvements and communicating suggested changes to all relevant stakeholders prior to implementation.
- Support Team Leader in periodically evaluating drug product specifications
- Lead any characterisation studies as required for Arecor products, determining cost, timelines and resource needs to complete study
- 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.

Job Description
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Principal Responsibilities: Technical leadership

- Scientific lead of the team, advising other team members on appropriate approaches to achieve the objectives of the studies
- Independently lead, design, plan and manage own studies as required to achieve objectives and those of Arecor 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.
- Lead experimental design and interpretation of results. Participate in laboratory activities e.g. trouble shooting, problem solving and assistance.
- Be a technical / scientific reference within Arecor with whom junior scientists can rely on to progress their projects

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.
- Ensures all direct reports read the appropriate RA and COSHH before performing any task
- Ensure tasks performed in the laboratory by themselves and direct reports are completed according to the relevant SOP and protocols following ALCOA principles.
- Ensure that all project data 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 Team Leader.
- Responsible 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 & Experience

- A BSc, MSc or PhD in Life Sciences or equivalent
- Significant experience (5+ years) of working within the pharmaceutical industry performing process development/scale up of drug product formulation.
- Recent knowledge and experience of working in a laboratory setting
- 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, MFI, UV, DLS, CE-SDS, IcIEF 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 ICH guidelines, in particular Q2R1, Q8, Q9 and Q11
- Experience of regulatory filling for FDA and EMA advantageous (IND and IMPD preparation)
- Formulation experience advantageous.
- 3+ years of Line management experience

Skills and Attributes

- Strong communication, planning, team working and organisational skills
- Strong management skills. Ability to manage a team with multiple projects and tasks concurrently and identify and prioritize activities based on value for the company
- Capability to identify future disruptive events that can affect projects quality and timelines and generate strategies that avoid or reduce its impacts on projects
- Self-motivated and able to work both individually and within a team
- 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
- Methodical, organised with an aptitude for detail.

Issued by: _____ Date: _____

Manager

Accepted by: _____ Date: _____

Job Holder