Job Description

Title:	Clinical Operations Leader (maternity cover)	**Department:**	Clinical and Regulatory Affairs
Reports to:	VP Clinical and Regulatory Affairs, QA	**Date Prepared:**	November 2021

Broad Function

This is a one-year, fixed contract position to cover maternity leave.

To lead the set-up, management and reporting of Arecor sponsored clinical trials in accordance with ICH GCP and applicable regulatory guidelines. To manage junior members of the department.

Principal Responsibilities

- Lead the day-to-day management of the Arecor clinical trial programme.
- Lead clinical programme budget discussions and forecasting activities.
- Lead clinical trial outsourcing activities and selection of vendors.
- Line manage Clinical Project Associate (1) and Clinical and Regulatory co-ordinator (1)
- Ensure Arecor sponsored clinical trials are set up and managed in compliance with ICH GCP and other relevant regulations.
- Support the regulatory activities in the department such as CTA application and scientific advice procedures
- Contribute to the content and writing of trial documentation.
- Act as a senior point of contact for clinical trial vendors including clinical research organisations, consultants and clinical sites.

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.
- Liaise with internal personnel at all levels of the business as required.
- Liaise with the wider team including site staff, consultants and other external third-party organisations as required.

Job Description

Education & Experience

- Educated to degree level in a biomedical discipline.
- Knowledge of the ICH GCP and regulatory guidelines relevant to Sponsor oversight of clinical trials.
- Experience of working in a commercial pharmaceutical setting.
- Experience in clinical trial management and delivery.
- Experience in early phase clinical studies.
- Experience in diabetes studies is an advantage.

Skills and Attributes

- Competent and organised self-starter with the ability to perform multiple tasks concurrently.
- Ability to work efficiently and effectively in a matrix environment.
- A flexible and willing attitude with the desire to develop knowledge.
- Liaises with other individuals as required to ensure plans remain on schedule.
- Methodical, organised and an aptitude for details.
- Excellent communication, planning, team working and organisational skills.
- Strong IT skills, including Microsoft Word, Excel, Outlook and PowerPoint.
- Maintain Arecor company values at all times.