Job Description

Title:	Clinical Project Associate	**Department:**	Clinical and Regulatory Affairs
Reports to:	Clinical Project Manager	**Date Prepared:**	February 2021

Broad Function

To provide support in the design, set-up, management and reporting of Arecor sponsored clinical trials in accordance with ICH GCP and applicable regulatory guidelines.

Principal Responsibilities

- Assist in the set up and management of Arecor sponsored clinical trials in compliance with ICH GCP and other relevant regulations.
- Contribute to the preparation and review of clinical trial Protocols, Investigator Brochures and other trial documentation.
- Prepare regulatory authority and ethics committee submissions.
- Act as the main point of contact for clinical trial vendors including clinical research organisations, consultants and clinical sites.
- Lead clinical site management activities including tracking clinical study progress and review of monitoring reports.
- Manage administrative tasks for study oversight including creation, review and maintenance of documentation required for the Trial Master File and Sponsor files.
- Participate in vendor and internal trial related meetings, including preparation of agendas and meeting minutes as required.
- Assist with wider dissemination of trial information and results including preparation of presentations and manuscripts where applicable.
- Assist with other clinical project activities to support the wider clinical development programme.

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 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.
- Early phase study experience desirable.

Skills and Attributes

- Communication, planning, team working and organisational skills are essential.
- Adapts style of communication to meet the needs of the audience and shares information with colleagues.
- Responds positively to team goals and works towards them, liaising with others to ensure plans remain on schedule.
- Identifies current problems quickly and accurately and recognises the need for solutions without being prompted.
- Deals positively with change and is able to highlight where changes in own plans will affect others or overall operational plans
- Asks questions to check own understanding of requests and actively listens and responds appropriately.
- Carefully follows all steps of procedures to complete all assigned tasks with accuracy and consistency.
- Analyses project requirements, assigns resources effectively, monitors implementation and delivers results in line with project goals.
- Strong IT skills, including Microsoft Word, Excel, Outlook and PowerPoint