



Job Title: Director Pre-Clinical Development

Department: Translational Research & Development (TRAD)

Location: Boston, MA

Reporting to: VP, Preclinical Development

The successful candidate will be a key member of the Translational Research and Development team with major responsibility in preclinical development including ADME, safety pharmacology and PK/TK studies in multiple animal species. The successful candidate will have a broad and extensive background in the areas of IND enabling preclinical development of the drug candidates to support the clinical studies as well as regulatory filings. Specifically, the candidate will have a demonstrated experience working with CROs in conducting GLP safety pharmacology and selected aspects of safety tox studies. The scope of activities includes, designing, budgeting, outsourcing, managing and conducting these safety pharmacology studies, and assay development. Further activities include writing and finalizing study reports in support of various regulatory filings. The successful candidate will have strong technical and project management skills. The position will report to the vice president, pre-clinical development TRAD.

The successful candidate will be a creative thinker and an effective team player with excellent communication skills needed for timely dissemination of the information to cross functional teams as well as seeking the necessary information for planning and conducting the work.

Specific Areas of Expertise Include:

- Experience working with CROs in developing protocols, budgets, timelines, and conducting IND enabling safety pharmacology studies.
- Work in close collaboration with external experts to coordinate and monitor the GLP pharmacology studies in multiple animal species.
- Proficient in designing and conducting *in vivo* safety pharmacology, PK/TK, and ADME studies.
- Additional experience with designing and managing ADA studies will be a plus.
- Prior experience in conducting and supporting IND/NDA enabling pre-clinical development activities.
- Writing and finalizing selected study reports for regulatory filings.

Job Responsibilities:

- Responsible for the IND enabling safety pharmacology, GLP PK/TK working with CROs and external SMEs / consultants.
- Providing key expertise in developing and managing IND/NDA enabling pre-clinical development programs. Managing and preparing the safety/tox risk assessment of the development programs.
- Developing strategic and creative initiatives within best industry practices and management of CRO contracts.
- Work with cross-functional teams to develop the scope of the safety/tox studies to defend and support clinical studies.
- Commitment to the success of the Rhythm's business in developing innovated therapeutics with a drive to succeed individually as well as contributing to the success of the team with knowledge and expertise; respect for teamwork and others.

Rhythm Pharmaceuticals, Inc
500 Boylston Street, 11th Floor
Boston, MA 02116
www.rhythmtx.com



Job Requirements:

- A Ph.D. degree and subsequent training in pharmacology or closely related field, such as, biochemistry, physiology, neurobiology etc.
- 8 years of experience in the pharmaceutical/biopharmaceutical industry contributing to the pre-clinical development of candidate therapeutics, including four years on preclinical pharmacology studies in multiple animal species.
- Prior experience in the pharmacology of obesity and satiety as well as knowledge of related animal models would be desirable.
- Knowledge of GLP requirements and regulatory guidelines (FDA / EMA / ICH).
- Management skills and a team-oriented approach are critical.
- Experience working with CROs and SMEs is a must with forging strong working relationships and contract managements.

(168)

This is not meant to be an exhaustive list of all responsibilities, duties, and skills required for this role. The role may be required to perform other related duties, as assigned.