Director, Toxicology and Pathology

MyoKardia, Inc.

Location: South San Francisco, CA USA

Apply: http://www.myokardia.com/careersOpp.php?p=job%2Fo4T18fwQ

MyoKardia is pioneering a precision medicine approach to discover, develop and commercialize targeted therapies for the treatment of serious and neglected rare cardiovascular diseases. Our initial focus is on the treatment of heritable cardiomyopathies, a group of rare, genetically-driven forms of heart failure that result from biomechanical defects in cardiac muscle contraction.

Our goal is to be the world's leading precision cardiovascular medicine company. Precision medicine involves discovering and developing therapies that integrate clinical and molecular information based on the biological basis of disease. This approach has led to the efficient discovery and development of transformative therapies in areas such as oncology, cystic fibrosis and hypercholesterolemia, but has yet to be broadly applied to cardiovascular diseases.

We have used our precision medicine platform to generate an initial pipeline of therapeutic programs for the chronic treatment of the two most common forms of heritable cardiomyopathy—hypertrophic cardiomyopathy, or HCM, and dilated cardiomyopathy, or DCM.

There are currently no approved therapies indicated for the treatment of HCM or DCM, including heritable DCM, all of which are chronic and debilitating diseases. Patients are typically treated with drugs that are indicated for broader cardiovascular disorders and do not address the underlying cause of the disease. As the disease progresses, patients have limited treatment options, such as surgical or other invasive interventions and heart transplant.

Launched in 2012 by Third Rock Ventures, MyoKardia was founded by world-class experts in cardiovascular disease, cardiac muscle biology and genetics.

Job Description:

The Director of Toxicology and Pathology will contribute to development of strategy and planning for Nonclinical Toxicology and Pathology for MyoKardia programs and be primarily responsible for execution of a subset of all programs. This position reports to the Head of Toxicology and Pathology in the Nonclinical and Pharmaceutical Development function.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

This position will be responsible for:

- Lead all aspects of toxicology and pathology assessment for a subset of MyoKardia Research and Development programs
  - Design and oversee toxicology and safety pharmacology studies
  - Evaluate and select Contract Research Organizations (CROs)
  - Peer review studies
  - Review and finalize reports
  - Develop overall toxicology strategy for each program assigned
- Represent Toxicology and Pathology on MyoKardia project teams
  - Participate as a key member of core project teams helping direct nonclinical development activities
  - Lead nonclinical subteams as needed
- Accountable for the execution of project toxicology plans
  - Responsible for delivering program studies on time and in budget
  - Monitors study progress and performs site visits and peer reviews
  - Supervise toxicologists within the department monitoring program studies.
- Support regulatory submissions and approvals through the timely provision of data and its analysis
- Support the selection of development candidates
- Lead the nonclinical contribution to IND's, Investigational Brochures, Regulatory Briefing Documents, and other relevant documentation for assigned programs
- Take primary responsibility for all toxicology study conduct and data analysis and interpretation, reporting and communication
- Ensure consistency of nonclinical content and scientific messages across publications and materials
- Use innovative technology, including state-of-the-art imaging, biomarker, and genetic analysis, to optimize our understanding of molecules in development at MyoKardia

EDUCATION/EXPERIENCE/SKILLS:

Education:

- DVM or MD with pathology training is required, preferably with diplomate status in appropriate organization (ACVP, ECVP, ABP, etc.)

- Ph.D. in an affiliated discipline is a plus but not required

Experience:

- Typically requires a minimum of 3-5 years of related experience and/or combination of experience and education/training research in the toxicology or biotechnology/pharmaceutical industry. Experience in cardiovascular drug development is desirable

Knowledge/Skills/Abilities:

- Solid understanding of Nonclinical drug development, ideally with relevant CV therapeutic area experience
- Expertise in toxicology and study design principles meeting GLP/ICH requirements, and other Regulatory considerations
- Leadership: Experience leading and motivating teams in a matrix environment is required. Proven interpersonal skills with ability to influence, resolve conflict and drive decisions among internal cross functional teams, executive management, and external teams
- Strategic Agility: Ability to develop and execute complex strategies
- Ability to effectively collaborate in and across multiple functions, and with internal and external stakeholders of various backgrounds and skill sets. Skilled in establishing a collaborative and respectful environment
- Demonstrated decision-making skills taking multiple perspectives into account and analytical skills are required; exercises sound business judgment that has broad organizational impact. Publication supporting these skills are a plus
- Communication: Excellent communication skills (both orally and written) is critical to the success of the role
- Business Excellence: Good at developing the processes necessary to get things done, knows how to organize people and activities, and knows what to measure and how to measure
- Demonstrated ability to interpret data into actionable items