Evofem Biosciences is a clinical-stage specialty biopharmaceutical company focused on discovering and developing innovative healthcare solutions that give women better control of their reproductive health. Evofem Biosciences is currently identifying and developing new and novel products that specifically address unmet needs in the areas of sexual and reproductive health, the prevention of acquisition of sexually transmitted infections, and products that address or promote general health and wellbeing. Evofem Biosciences' sole focus is bettering the lives of women by offering innovative, woman-controlled contraceptive options. The Corporate Social Responsibility partnership between Evofem Biosciences and WCG is an initiative focused on the convergence of not-for-profit and for-profit entities for the purpose of improving the reproductive health and well-being of girls and women everywhere.

Director, Nonclinical Research & Product Development

Summary:

The Director, Nonclinical Research & Product Development will lead, organize, and manage the company's nonclinical product development and product support activities. S/he is able to generate a research plan, design experimental protocols and coordinate the work of external advisors, vendors and CROs. S/he is able to work closely with Quality and Manufacturing counterparts to fulfill CMC product requirements. S/he is a knowledgeable resource for other departments including Regulatory Affairs, Quality Assurance, Clinical Development, Sales and Marketing and Business Development.

Job Responsibilities:

- Initiate and drive nonclinical research in support of existing and future products in Evofem's portfolio.
- Develop technical plans for nonclinical development projects and oversee implementation of those plans.
- Lead the design and interpretation of results of in vitro and animal studies in consultation with external scientific advisors.
- Evaluate contract research organizations or academic laboratories for study placement.
- Manage vendors and external collaborators for nonclinical projects.
- Ensure new and existing products meet appropriate technical specifications and quality guidelines including review and signoff of specifications, test methods, protocols and technical reports.
- Contribute to study summaries and appropriate sections of global regulatory submissions.

- Participate and represent nonclinical in due diligence and business development activities.
- Oversee budget and execution of nonclinical research strategy including timelines, milestones, methodological approaches, expected results and necessary resources.
- Provide strategic scientific and operational advice, regular updates, documentation, and communication of project results across all organization levels as appropriate.

- Perform other duties as assigned or needed.

Competencies:

- Must be detailed oriented, possess excellent time management skills, be well organized, able to contribute independently and display a professional demeanor.
- Must possess excellent communication and technical writing skills, strong interpersonal skills, and ability to work with others in a positive and collaborative manner; able to communicate with sense of urgency to internal and external customers.
- Excellent experimental design, trouble shooting and quantitative data analysis skills
- Ability to lead, supervise and coordinate the work of external consultants and vendors and ensuring adherence to established timelines.

Education and Qualifications:

- Ph.D. in Biology, Chemistry, Biochemistry, or related field with minimum 5 years' experience in research and product development OR Master's degree in related field with minimum 10 years' experience. Experience in reproductive health or related products preferred.
- Experience identifying and managing external vendors, including contract research organizations.
- Experience in managing complex projects and/or certification in project management preferred.
- Competency in evaluating bioanalytical results and reports.
- Knowledge of regulatory guidance and requirements related to nonclinical development and CMC activities.
- Understand and adhere to GMP and GLP policies and procedure

Evofem Biosciences provides a competitive salary and generous benefits package including medical, dental, vision coverage, 401k, paid vacation and Holidays.

To apply for this position with Evofem Biosciences
please submit a cover letter and your CV and salary requirements at www.evofem.com
Evofem Biosciences is an Equal Opportunity Employer

No agencies please