Evofem Biosciences, Inc., (NASDAQ: EVFM) is a commercial-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Evofem Biosciences aims to advance the lives of women by developing innovative solutions, such as woman-controlled contraception and potential protection from certain sexually transmitted infections (STIs). The Company's first commercial product, Phexxi™ (lactic acid, citric acid and potassium bitartrate), is approved in the United States for the prevention of pregnancy. The Company is advancing EVO100 for the prevention of urogenital transmission of both Chlamydia trachomatis infection (chlamydia) and Neisseria gonorrhoeae infection (gonorrhea) in women.

We are a growing team based in San Diego, CA. Our sole purpose is also our soul purpose: to improve the lives of women. We are committed to discovering and developing innovative healthcare solutions that put women first.

Director, Clinical Operations

Job Summary:

The Director of Clinical Operations will work closely with the VP (Clinical Affairs & Pharmacovigilance) and will provide project management and oversight of conduct of Evofem clinical trials in accordance with ICH GCP regulations, maintaining compliance and supporting regulatory authority submissions.

Job Responsibilities:

These may include but are not limited to:

- Direct and oversee the operation of the clinical program(s) to ensure compliance with regulatory requirements.
- Ensure adequacy of data acquisition and management, and timely completion of studies and associated projects.
- Identify and communicate project objectives, propose innovative solutions to potential obstacles in study conduct, study sites, or with CROs.
- Ensure adequate study resources are in place to successfully complete clinical project and programs on-time and, on-budget.
- Evaluate CROs for their ability to execute clinical trial work, compare budgets and timelines and make recommendations to senior management.

- Coordinate with departmental teams to ensure appropriate fiscal oversight, including management of vendor scopes-of-work and change orders.
- Oversees the operational aspects for the development and delivery of standard study protocols, informed consents, vendor selection/management and site selection and recruitment strategies.
- Oversee vendor and site qualification activities in conjunction with Clinical Quality Assurance, Manufacturing and Tech operations.
- Oversee management and maintenance of Trial Master File.
- Support regulatory audits and inspections.
- Provide guidance on all clinical operation logistics associated with execution of clinical studies (including clinical supplies, sample shipments etc.).
- May contribute to the development of SOPs and other procedural documents.

Competencies:

- Must have excellent accountability, facilitation, organizational, analytical, and time management skills.
- Experience considered relevant includes clinical or basic research in Biotech, Pharmaceutical or Contract Research Organization.
- In-depth experience with drug development issues.
- A good understanding of GLPs, GCPs, and ICH Guidelines.
- Must be detailed oriented, possess excellent time management skills, be well organized, and display a professional demeanor with a high focus on quality, compliance, and responsibilities.
- Must be able to work as a team member, multi-task, and maintain day-to-day activities while being responsive to changing priorities.
- Must possess excellent communication and technical writing skills, strong interpersonal skills, and ability to work with others positively and collaboratively; able to communicate with a sense of urgency to internal and external customers.

Supervisory Responsibility:

- This position may manage internal and external representatives.

Education and Qualifications:

- Advanced scientific degree a plus (MS in biological sciences, Pharm D or related discipline) with at least 10 years' experience working in the biotechnology/pharmaceutical industry (an equivalent combination of experience and education may be considered).
- Prior experience managing third parties and external service providers (worldwide) and consultants.

- Excellent writing skills as they relate to the preparation of clinical and regulatory documents.
- Excellent interpersonal skills with strong oral/written communication and presentation skills.
- Excellent negotiation skills and a tactful approach that leads to high value on services obtained and outcomes achieved.
- Demonstration of cross-functional understanding related to drug development.
- Good judge of risks and a keen ability to analyze options and manage outcomes.
- Familiarity of Regulatory Affairs as applicable to clinical data and report filings.
- Excellent collaboration skills with strong attention to detail and the ability to multi-task and manage complexity.
- Excellent computer skills in the following programs: MS Word, PowerPoint, and Excel.

Travel:

- Ability to travel 10-20% domestic.

Evofem Biosciences provides a competitive salary and generous benefits package including medical, dental, vision coverage, 401k, paid vacation and Holidays.
Evofem Biosciences is an Equal Opportunity Employer
No agencies please