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.

Manager, Regulatory Affairs

Summary:

The Manager of Regulatory Affairs (RA) will be responsible for managing regulatory plans for Evofem products, label expansions, and/or new indications. The position will represent RA on cross-functional project teams. The Regulatory Affairs Manager will be responsible for ensuring completion of all regulatory submissions relevant to assigned projects per timeline.

Essential Duties & Responsibilities:

- Execute regulatory plans, including management and participation in the effort to ensure timely regulatory submissions for Evofem's products to meet corporate goals (including INDs, NDAs, CTAs, MAAs, 501(k)s, PMAs, CE product Certifications, Design Dossiers).
- Assist with reviewing CMC strategy and CMC submissions, identify any CMC issues for pharmaceutical development and post marketing projects.
- Assist in the maintenance of general regulatory compliance, including local and federal licensure, promotional compliance, and maintenance and management of regulatory policies and procedures.
- Participate in FDA facility inspections, as needed.
- Monitor and maintain applicable timelines, budgets and workflow associated with regulatory projects
- Effectively communicate within RA/QA, Legal, Medical and Commercial leads.
- Perform other duties as assigned.

Competencies:

- Excellent interpersonal, communication, analytical and managerial skills.
- Ability to work successfully within cross-functional teams and influence appropriate plans and actions.
- Strong attention to detail, establishing priorities, scheduling and meeting deadlines.
- Must be able to work in a fast-paced environment with demonstrated ability to manage multiple competing tasks and demands.
- Ability to work independently, take initiative and complete tasks to deadlines.

Supervisory Responsibility: None

Education and Qualifications:

- BA/BS in chemistry, biology, engineering or related pharmaceutical field
- 5-7 years of pharmaceutical/biotech drug and medical device development
- Knowledge of U.S. Pharmaceutical and/or Medical Device regulations, standards, policies and guidance documents required.
- Must have FDA Regulated Industry experience.
- Highly proficient communication skills, both written and verbal. Able to clearly and concisely explain complex scientific concepts to audiences with extensive technical expertise and to those without.

Travel:

- Ability to travel 10- 20% domestically

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