Evofem Biosciences, Inc., (NASDAQ: EVFM) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Evofem Biosciences exists 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 is leveraging its proprietary Multi-purpose Vaginal pH Regulator™ (MVP-R) platform to develop AMPHORA®, which if approved will be the first on-demand and female controlled MVP-R birth control method in the U.S.

We are a growing 40+ person 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.

CMC Development Specialist

Job Summary:
The CMC Development Specialist will report to the Director, CMC and is responsible for final review and quality control of all analytical data, method development, qualification, validation and transfer for drug substances and drug products generated by external laboratories and manufacturers. Implementation of internal processes and generation of SOPs to streamline those processes will be required. All reviewed data/documents will then be routed to our Quality Assurance group for final review and filing in the document control system.

Job Responsibilities:

- Perform technical reviews of analytical and stability data, trending analyses, method validations, transfer protocols, as well as experimental reports.
- Perform analysis and identify trends in the inspection of finished products, in-process materials and bulk raw materials and recommends corrective actions when necessary.
- Develop processes and tests to determine the appropriate quality control analysis are performed.
- Assemble data tables for regulatory submissions.
- Review master batch records and executed batch records.
- Review controlled documents, develop and implement SOPs for Technical Operations Department.
- Work closely with Quality Assurance on GMP-compliant documentation management.
- Assist Quality Assurance during inspections, audits and due diligence activities.

- Perform technical audits of contract analytical laboratories.
- Develop formal written reports to communicate audit results to management and regulatory compliance agencies, as applicable.
- May facilitate work of external auditors during on-site visits.
- Assist in troubleshooting OOS and OOT root causes.

Competencies:

- 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 in a positive and collaborative manner; able to communicate with sense of urgency to internal and external customers.
- Leadership skills with the ability to maintain an atmosphere of positive growth and achievement; a self-starter with minimum oversight required to accomplish goals.
- Ability to define problems, collect data, establish facts, and draw valid conclusions.
- Demonstrated experience with generating metrics/trending to ensure efficiency and effectiveness.

Supervisory Responsibility: None

Education and Qualifications:

- Minimum B.A. or B.S. in scientific related field.
- 3-5 years of relevant experience in Biotech or Pharmaceutical industry.
- Extensive analytical development background with experience reviewing analytical data and analytical development activities from external CRO/CMOs.
- Broad knowledge and experience within the cGMP environment, Quality and Regulatory Affairs and strong knowledge of ICH regulations, US and EU Pharmacopeia.
- Excellent collaboration skills with strong attention to detail and the ability to multi-task and manage complexity.
- Strong interpersonal and organizational skills and excellent verbal and written communication skills are required.

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