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.

Quality Assurance Specialist II – QA Operations

Summary:

The QA Specialist is responsible for providing guidance in the principles and application of quality assurance and compliance. The QA Specialist shall demonstrate high level of involvement in implementation and continuous improvement of quality assurance philosophy and practices to ensure that Evofem's products are manufactured, tested, stored, and distributed according to current Good Manufacturing Practices (cGMP) and applicable requirements as per 21CFR 210/211/820, ISO 13485, EU, ICH and international regulations.

The QA Specialist shall work with manufacturing operations, supply chain, clinical, regulatory personnel and with external counterparts at contract organizations to assure compliance with the company quality policies, and documentation associated with development, manufacture and distribution of clinical and commercial product. Additional specialized QA responsibilities may be assigned.

Essential Duties & Responsibilities:

- Develops, evaluates and revises Evofem QMS processes/procedures to ensure compliance with GMP/QSR/QMS regulations and guidelines.
- Supports various QMS processes including NCR, Internal Audits, Supplier Management, Quality Certificates, Customer Complaints, Analysis of Data, and CAPA.
- Supports QA review and approval of production batch records and testing results, specification changes, product non-conformances, deviations and protocols/reports.
- Participates in internal audits and/or gap analysis to ensure evaluation of critical systems, processes and equipment are in-compliance with all regulatory requirements; identifies risks and communicates any gaps for quality processes optimization.

- Supports the Quality Unit during internal/external audits, FDA.
- Participates and/or leads quality projects and teams for continuous improvement of internal quality system infrastructure and external manufacturing processes.
- Ensures completeness, accuracy and compliance of all documentation including CAPA management.
- Performs and manages training of internal personnel to permit execution of required tasks and ensure compliance to regulatory requirements/Policies/SOPs.
- Develops and prepares quality data/metrics for Management Review.
- Maintains up-to-date knowledge of cGMP regulatory issues, industry and affiliated publications, standards and guidance.

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 implementation/improvement of quality system and generating metrics/trending to ensure efficiency and effectiveness.
- Experience in auditing and FDA inspections preferred; previous CQA or auditor training is a plus.

Supervisory Responsibility:

None

Education and Qualifications:

- Bachelor's degree in life science or biological science and/or equivalent combination of education and related work experience in quality systems operations.
- 3-5 years of QA experience in pharmaceutical FDA regulated industry (some may be with medical devices and/or biologics),
- Strong knowledge of GMP/QSR regulations, ICH guidelines and their relevant ISO counterparts; additional knowledge of GLP/GCP a plus.

- Requires strong computer skills, Microsoft Office Applications (Access, Excel and Word).
- Experience with eQMS/eDMS/eLMS applications preferred.

Travel:

Expected travel 10%.

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