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.

Senior Manager/Manager Quality Assurance

Summary:

The Senior Manager/Manager of QA is responsible for providing Quality leadership and oversight to ensure that operations for Evofem's products are manufactured, tested, stored, and distributed according to current Good Manufacturing Practices (cGMP) and other applicable regulations.

The manager shall work with Manufacturing operations, supply chain, clinical, regulatory personnel and with external counterparts at contract organizations to ensure compliance with the company quality policies, and documentation associated with development, manufacture and distribution of clinical and commercial product as per requirements of 21CFR 210/211/820, ISO 13485, EU, ICH and international regulations. Additional specialized QA responsibilities may be assigned.

Essential Duties & Responsibilities:

- Develops, evaluates and revises Evofem QMS processes/procedures to ensure compliance with GMP/GLP/GCP regulations and guidelines.
- Manages various QMS processes including Document & Records Control, NCR, Internal Audits, Supplier Management, Quality Certificates, Training, Customer Complaints, Analysis of Data, Design & Development, and CAPA.
- Supports all aspects of Supplier Quality Management Program including supplier qualification audits/assessments, product quality assessments, ongoing supplier evaluation/audits/assessments, develop/approve Quality Agreements and maintenance of the Approved Supplier List.

- Provides quality leadership and guidance for equipment qualification, facility commissioning and qualification, manufacturing process validations and software validation.
- Ensures that contracted suppliers comply with GMP/GLP/GCP regulatory requirements and relevant SOPs.
- Provides QA review and approval of production batch records and testing results, specification changes, product non-conformances, deviations and protocols/reports (e.g., validations, qualifications, capability, stability).
- Executes Gap Analysis and/or Risk Assessments (HA, FMEA) to ensure evaluation of critical systems, processes and equipment are in-compliance with all regulatory requirements (e.g., cGMPs, FDA Guidelines, USP, ISPE, ISO).
- Leads, manages or participates in quality projects and teams for continuous improvement of internal quality system infrastructure and external manufacturing processes.
- Represent the Quality Unit during internal/external audits, FDA and other regulatory inspections.
- Alerts line management of significant quality, compliance, supply and safety risks, often requiring the coordination of activity across organizational units. Exercises independent judgment.
- 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.
- Maintain 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, a self-starter and display a professional demeanor with a high focus on quality, compliance, and responsibilities.
- Leadership skills with the ability to develop employees and 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.
- 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.
- Must be able to work as a team member, maintaining day-to-day activities while being responsive to changing priorities.

- Demonstrated experience with implementation/improvement of quality systems to ensure efficiency and effectiveness.
- Experience with the development and implementation of current validation systems in the pharmaceutical industry.
- Experience in developing and generating quality system metrics/trending.
- Extensive knowledge of Root Cause Analysis / Risk Management / Good Manufacturing Practices / Quality System Regulations and ISO Standards is required.
- Experience in auditing and FDA inspections preferred.

Supervisory Responsibility:

Some direct supervisory responsibilities, as required. Responsibilities include interviewing, hiring, and training employees; planning, assigning, and directing work; appraising performance; rewarding and disciplining employees; addressing complaints and providing solutions.

Education and Qualifications:

- Bachelor's degree in life science or biological science with related work experience in quality and/or regulatory systems operations.
- 5-10 years of QA experience in pharmaceutical FDA regulated industry (some may be with medical devices and/or biologics), 3-5 years of experience working with CMO and business partners.
- Strong knowledge of GMP/QSR regulations, ICH guidelines and their relevant ISO counterparts; additional knowledge of GLP/GCP.
- Requires strong computer skills, Microsoft Office Applications (Access, Excel and Word).

Travel:

Expected travel 20% to 25% -some may be international.

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