Position Posting:

Vice President Quality & Regulatory Affairs

Ripple Therapeutics Corporation is a clinical stage, privately held company that is focused on ophthalmic therapeutics with controllable, sustainable drug delivery. The core feature of Ripple's Epidel™ technology is the ability to engineer sustained-release pharmaceuticals with zero-order release kinetics without the use of polymers or excipients. Ripple has a full product pipeline in development. www.rippletherapeutics.com

Position Summary:

Ripple is seeking a highly collaborative senior executive with significant quality leadership experience to drive quality across the organization. Ideally, this individual would also have regulatory experience to lead and manage the preparation, review and submission of documents to health care regulatory authorities around the globe.

Reporting to Ripple's President & CEO, this individual will be a key member of the leadership team, having shared responsibility for the company's strategic direction.

Essential Functions:

- Key accountability for ensuring quality, safety and regulatory compliance for Company products and processes.
- Key member of the Senior Leadership Team. Effectively communicates important Quality Assurance and Compliance information to management and other departments of the organization and externally as required.
- Promotes the development of a company-wide culture of quality awareness and understanding of the key elements related to the quality system and regulatory compliance requirements.
- Enhances key elements of the quality system through continuous improvement in the quality system and documentation, including eQMS implementation and maintenance.
- Evaluates information to verify that the pharmaceutical products Sponsored by Ripple comply with FDA regulations.
- Responsible for regulatory strategy and working with regulatory consultants
- Is the front person during regulatory inspections, if applicable.
- Meets Regulatory requirements and timely responses to Regulatory Letters and Observations, if applicable.

Quality Responsibilities

- Oversees Quality Assurance, setting quality goals and objectives consistent with established company and management goals, as well as FDA/QSR, EMA/Eudralex, ICH, GMP and ISO quality standards, as applicable.
- Promotes the development of a company-wide culture of quality awareness and understanding of the key elements related to quality system and regulatory compliance requirements.
- Serves as the Quality management representative for regulators, notified bodies and customer audits.
- Maintains knowledge of existing and emerging quality standards, regulations and guidance documents, as they pertain to Ripple products. Interprets changes to rules and standards and ensures that they are communicated through corporate policies as well as in Supplier Agreements.
- Supports and has ownership of audit processes for Supplier Qualification and Maintenance. Works cross functionally, in-house and externally, to facilitate the Supplier Selection process.
- Has extensive experience in the selection and qualification of GxP suppliers and the transferring ot GxP responsibilities as well as preparing, reviewing and approving the corresponding quality agreements.
- Works with SMEs in specific disciplines, both in-house as well as consultants, as needed to ensure expert technical review of controlled documents.. Reviews and approves controlled documentation related to GxP activities outsourced to Qualified Suppliers, including deviations, OOS investigations, CAPAs, risk assessments, etc.
- Creates a quality documentation system by writing and updating quality assurance procedures.
- Supports Qualified Suppliers in the development of protocols for test method validations, design and process verifications and validations, biocompatibility, sterilization, shelf life, stability, and risk management to ensure compliance.
- Develops departmental budget for Quality Assurance & Compliance.
- Develops the Quality Assurance Unit by recruiting, selecting, orienting, and training QA staff.
- Ensures quality by planning, monitoring, and appraising job results.

Regulatory Responsibilities

- Responsible for driving implementation of and continued compliance with global regulatory requirements, interpreting and appliying pertinent laws and regulations governing company products to meet business objectives
- Leads development, implementation and maintenance of regulatory processes at a company-wide level
- Leads worldwide regulatory submissions for pharmaceutical and combination products

- Supports the development of regulatory strategies and application of the strategies to align with the business plans for a particular product
- Actively works with Product Development Teams and/or commercial partners to ensure appropriate planning, tracking, and alignment of contents and timelines for regulatory submissions across indications for US and International regulatory submissions
- Serves as main company contact with Regulatory Authorities or, where appropriate, works in conjunction with regulatory consultants or CROs to coordinate with local country regulatory representation
- Demonstrates sound understanding of related fields (e.g., CMC, product / process development, quality assurance) and ability to solve complex problems in collaboration with colleagues in other functions.
- Monitors the regulatory environment regionally/globally and provides assessments for the impact of new and changing regulations on the company's areas of interest. Ensures new regulations or changes to existing regulations are communicated throughout the organization through company policies, procedures, and training
- Represents the Regulatory function on project teams to ensure alignment of regulatory strategy and plans with the team objectives
- Develops and supports training for global regulatory processes and system implementations

Required Education and Work Experience:

- University degree in Life Sciences or a related field
- 10+ years of experience including Quality and international Regulatory Affairs
- 5+ years of recent management experience in a regulated healthcare products environment
- Experience in pharmaceutical and/or combination products required; specific experience in ophthalmology preferred
- Successful track record of managing regulatory submissions in key global markets
- Successful track record of implementing and managing quality standards
- Experience in leading RAQA teams to support complex product development processes
- Ideal candidate will have had experience working in both large organizations and early stage start-ups

Required Skills and Competencies:

- Enjoys developing innovative solutions to complex problems
- Strong ability to work collaboratively in a dynamic fast-paced environment.
- Well organized, analytical and self-confident

- Strong research abilities, experience in conducting detailed literature reviews and statistical analyses
- Strong communication skills and interpersonal skills, ability to coach and mentor
- Builds team cohesiveness by leading, influencing and motivating team members
- Likes to have fun

To Apply:

- Please submit resumes in confidence to careers@rippletherapeutics.com with "VP QA-RA" in the subject line.
- Ripple Therapeutics welcomes and encourages applications from people with disabilities. Accommodations are available on request for candidates taking part in all aspects of the selection process.
- Compensation, including benefits and equity, is competitive and commensurate with experience.
- This is a great opportunity to work with engaged, committed and dedicated colleagues in an innovative and progressive environment.
- We thank you for your interest. Only those candidates selected for interviews will be contacted.