Position Posting:

Vice President Operations

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 addressing multiple $1B+ ophthalmic therapeutic applications with significant unmet needs. The lead program is currently in a Phase II trial with promising early results. The lead program has been licensed to Laboratoires Thea for North America and Europe. Other products are in various stages of development. www.rippletherapeutics.com

Position Summary:

Ripple is seeking to hire a Vice President of Operations to lead Ripple's later stage operational initiatives. This individual has significant experience in global development of pharmaceutical products from Phase II through to Commercial, including oversight of Manufacturing, Quality and Regulatory Compliance. The individual has demonstrated experience in leading CMC efforts through commercialization. This includes experience managing CDMOs to ensure cost, schedule and performance objectives are achieved; Quality Agreement compliance is maintained and Manufacturing processes lead to efficient and cost effective commercial production.

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:

- Lead late stage operational initiatives to execute all requirements in the product development cycle to effectively and expeditiously deliver products to market including managing the scale up and GMP manufacturing for Phase III through commercial materials.
- Grow, develop and manage the internal operations team to support Phase III through commercial CMC development.
- Manage the selection, qualification and management oversight of GxP suppliers including the transferring of GxP responsibilities as well as preparing reviewing and approving the corresponding Quality Agreements.
- Work with SMEs in specifc disciplines, both in-house as well as counsultants, as needed, to ensure expert technical review of controlled documents and processes. Review and approve controlled documentation related to GxP activities outsourced to Qualified Suppliers including deviations, OOS investigation, CAPAs, Risk assessments, etc.
- Manage Qualified Suppliers in the development of protocols for test method validations, design and process verifications and validations, biocompatibility, sterilization, shelf life, stability, and risk managementto ensure compliance.
- Enhance key elements of the quality system through continuous improvement in the quality system and documentation, including eQMS implementation and maintenance.
- Effectively communicate important Quality Assurance and Compliance information to management and other departments of the organization and externally as required.
- Promote the development of a company-wide culture of quality awareness and understanding of the key elements related to CMC, quality systems and regulatory compliance requirements.
- Ensure that pharmaceutical products sponsored by Ripple comply with US and OUS regulations as required.
- Develop and manage the departmental budget for late stage operational initiatives.

Required Education and Work Experience:

- University degree in Life Sciences or a related field
- 15+ years of experience including CMC process and scale up, quality and global regulatory compliance
- 5+ years of recent management experience in a regulated healthcare products environment
- Successful track record in overseeing the manufacturing and commercialization of pharmaceutical and/or combination products required; specific experience in ophthalmology preferred
- Ideally has worked in both large companies and smaller start ups and prefers the pace and culture of an early stage venture
- Successful track record of leading Teams in the implementing and managing quality standards

Required Skills and Competencies:

- Seeking candidates who are adaptable, team-oriented and have a "roll-up-your sleeves" mindset
- Must be capable at both strategic vision and tactical execution
- Enjoys developing innovative solutions to complex problems
- Strong ability to work collaboratively in a dynamic fast-paced environment.
- 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.