QUETZAL Tx

Vice President, Quality Assurance/ Chief Quality Officer

ABOUT THE COMPANY:

Quetzal Therapeutics is dedicated to transforming the future of medicine by addressing unmet medical needs in oncology and rare diseases. Through cutting-edge science and pioneering innovation, we develop breakthrough therapies that improve patients' lives. Our mission is to push the boundaries of treatment possibilities, delivering hope and life-changing solutions to those who need them most.

Quetzal Therapeutics is a biopharmaceutical company focused on the development of treatment for hematologic malignancies. The company's lead product is QTX-2101, a novel paradigm for treating patients with AML/APL. The company plans to initiate Phase III clinical trials by late-2025, with registration-enabling activities ongoing. Quetzal is also developing a pre-clinical asset QTX 2102, an advanced, next-generation antifungal and antiparasitic therapy designed to enhance efficacy while minimizing toxicity. By leveraging improved formulations and targeted delivery, this novel treatment aims to overcome the limitations of conventional therapy, offering a safer and more effective solution for life-threatening infections. We are in active portfolio expansion mode with additional programs being introduced into development.

Position Summary

The Vice President, Quality Assurance (VP QA) / Chief Quality Officer (CQO) will be a key member of the leadership team responsible for establishing and leading Quetzal Therapeutics' Quality organization. This individual will design, develop, and execute a comprehensive Quality Management System (QMS) covering clinical development, manufacturing (CMC), and supply chain operations. The role oversees all aspects of GxP compliance—including GCP, GLP, and GMP—ensuring the quality, safety, and regulatory compliance of investigational products as they advance through clinical trials toward commercialization. This is a high-impact leadership role with significant influence on corporate strategy, regulatory success, and operational excellence.

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Key Responsibilities

Strategic Leadership

- Establish the company's Quality vision, strategy, and culture, ensuring a strong focus on compliance, continuous improvement, and patient safety.
- Partner with the executive team to support corporate strategy, regulatory submissions, and global development programs.
- Serve as a key interface with health authorities (FDA, EMA, MHRA etc.) and industry forums on all quality-related matters.

Quality Systems & Compliance

- Design, implement, and maintain a fit-for-purpose Quality Management System (QMS) for a growing clinical-stage biotech.
- Ensure compliance with global regulatory standards (FDA, EMA, ICH) across all GxP domains (GCP, GMP, GLP, GDP).
- Oversee SOP development, policies, quality systems, and governance frameworks that meet both current needs and scalability for future growth, including regulatory filings and potential commercialization/launch readiness.
- Lead inspection readiness and management of external inspections and internal/external audits (clinical, manufacturing site, CRO/CMO, vendors).

Clinical Development Quality (GCP, GLP)

- Oversee clinical quality assurance activities, including monitoring CROs, clinical sites, ancillary vendors, and laboratories.
- Ensure quality oversight of clinical trial materials and processes, including informed consent, data integrity, and patient safety reporting.
- Develop and manage risk-based approaches to trial monitoring and compliance.

CMC & Manufacturing Quality (GMP, Supply Chain)

- Guide quality oversight of Contract Manufacturing Organizations (CMOs), Contract Development and Manufacturing Organizations (CDMOs), and testing laboratories.

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- Ensure GMP compliance across drug substance and drug product manufacturing, packaging, labeling, and distribution for clinical use.
- Establish robust CMC quality systems for batch release, deviations, CAPAs, change controls, tech transfer, and product lifecycle management.

Leadership & People Management

- Build and lead a high-performing Quality team as the company scales.
- Identify and oversee consultant networks and vendors to support internal quality initiatives
- Provide coaching, mentorship, and leadership across QA, QC, and compliance functions.
- Foster a culture of quality, accountability, transparency, continuous improvement, and cross-functional collaboration.

Qualifications

Required:

- Advanced degree (MS/PharmD/PhD) or relevant scientific background (chemistry, biology, pharmacy, engineering).
- 15+ years of progressively senior Quality Assurance leadership experience in the biopharma industry, including late Phase 2/3 clinical-stage development or commercial readiness.
- Demonstrated expertise in small molecules and CMC quality.
- Broad experience with global GxP regulations (GMP, GCP, GLP, GDP).
- Experience establishing and leading Quality organizations in high-growth or early-stage biotech environments.
- Demonstrated success in leading regulatory inspections and interactions (FDA, EMA, MHRA, etc.).

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Preferred:

- Prior experience as a head of Quality (QA/CQO) in a biotech or pharmaceutical company.
- Familiarity with global regulatory frameworks and ex-U.S. regulatory agencies.
- Strong understanding of risk management frameworks, compliance systems, and digital quality tools/eQMS systems.
- Proven record of scaling organizations from early-stage clinical development to commercial readiness.

Leadership Competencies

- Strong executive presence with ability to influence and collaborate with C-suite, board members, and investors.
- Deep commitment to integrity, transparency, and ethical business practices.
- Entrepreneurial mindset; comfortable in a fast-paced, resource-constrained, high-growth biotech environment.
- Exceptional communication, negotiation, and organizational skills.

POSITION: Full-Time, Exempt, Flexibility for Remote Work

Reports to: Chief Executive Officer

Why Join Quetzal?

This role provides an exceptional opportunity for an experienced and visionary regulatory leader to shape the future of innovative therapies at a nimble, growth-oriented biotech company. The position offers broad exposure to all aspects of CMC and clinical development, enabling significant strategic and operational impact across the product lifecycle.

DISCLAIMER: *The list under Role Responsibilities is not exhaustive but are merely the most accurate lists for the current job. Management reserves the right to revise the job description and to require that other tasks be performed when the circumstances of the job change.*

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EEO Statement: *Quetzal is proud to be an equal opportunity workplace. We are committed to equal employment opportunity regardless of race, color, religion, sex, sexual orientation, gender identity, age, national origin, disability, protected veteran status, and any other characteristic protected by law, rule, or regulation.*