QUETZAL Tx

Senior Director, CMC Regulatory Science

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.

SUMMARY OF ROLE:

The Senior Director, CMC Regulatory Affairs plays a pivotal senior leadership role within Quetzal Therapeutics, functioning as the principal architect of global Chemistry, Manufacturing & Controls (CMC) regulatory strategies. This position is responsible for leading, developing, and executing comprehensive regulatory plans that span the full product lifecycle—from early development through post-market maintenance—for both innovative and platform products. The candidate will provide high-level expertise and direction, ensuring all CMC submissions are timely, robust, and compliant with the evolving landscape of global regulations. The role requires strong collaboration across functions, leadership in responding to regulatory challenges, and strategic partnership with both internal and external stakeholders.

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RESPONSIBILITIES:

Strategic Leadership and Planning

- Develop and implement global CMC regulatory strategies that ensure regulatory approval, accelerate time-to-market, and support long-term commercial success of the product portfolio.
- Serve as the primary regulatory authority for all CMC matters, proactively advising executive and project teams on global regulatory frameworks, standards, and trends impacting product development and commercialization.
- Drive and oversee the preparation, submission, and maintenance of high-quality CMC content for investigational and marketing applications including INDs/CTAs, NDAs, MAAs, IMPDs, and global supplements and amendments.
- Anticipate and address regulatory hurdles, balancing scientific, technical, and regulatory considerations to mitigate risks and capitalize on opportunities.

Regulatory Submission and Compliance

- Coordinate and lead the authoring, critical review, and approval of CMC sections for regulatory submissions, ensuring alignment with business strategy, scientific content, and regulatory requirements.
- Maintain current knowledge and interpret evolving requirements and guidance from global regulatory agencies (FDA, EMA, ICH, etc.), ensuring best practices are integrated into agency filings and responses.
- Oversee preparation of regulatory assessments for product/process changes, deviations, and validations, including robust change control management strategies.
- Champion the creation and maintenance of compliant, inspection-ready CMC documentation and regulatory databases, supporting audits and inspections.

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Agency Interactions and External Engagement

- Spearhead global health authority interactions relating to CMC, including preparing briefing documents, coordinating meetings (e.g., pre-IND/IMPD, End-of-Phase, pre-NDA), and formulating responses to regulatory queries and deficiency letters.
- Build and nurture relationships with regulators and external industry bodies, representing the organization's position and advocating effectively for company and patient interests.
- Assess impact of new and emerging CMC regulations and guidance documents, ensuring prompt implementation or advocacy as needed.

Cross-functional and Matrix Leadership

- Serve as a senior-level advisor to functional heads across Research, Process Development, Manufacturing/Technical Operations, Quality, Clinical, and Supply Chain, ensuring alignment between CMC regulatory strategy and business objectives.
- Facilitate cross-team training and knowledge-sharing to enable best practices in regulatory compliance, submission authoring, and CMC change management.
- Establish effective partnerships with external vendors, CMOs/CDMOs, consultants, and other collaborators to ensure submission readiness and resolution of regulatory issues.

Resource Management

- Oversee departmental and project budgets, ensuring optimal resource utilization for regulatory activities.
- Lead or contribute to internal regulatory initiatives and process improvements, continuously enhancing submission quality and operational efficiency.

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REQUIREMENTS:

- Education: Advanced degree (MS, PhD, or PharmD) in a relevant scientific field (chemistry, biology, pharmacy, engineering).
- Experience: Minimum 10–15 years of progressive CMC Regulatory Affairs experience in biopharma or biotech, including direct leadership of teams and regulatory projects.
- Demonstrated expertise in global CMC regulatory frameworks (FDA, EMA, ICH), including hands-on experience with successful authoring and management of INDs, IMPDs, NDAs, MAAs, and associated supplements/variations.
- Proven success leading CMC regulatory activities from preclinical through late-stage/commercial programs, including change controls, post-approval compliance, and life-cycle management.
- Strong business acumen and the ability to manage priorities, deadlines, and competing demands within a small, dynamic organizational setting.
- Outstanding communication—verbal, written, and presentation—skills with the ability to influence, negotiate, and drive consensus across multiple levels.

Desired Skills & Attributes

- Strategic, analytical thinker comfortable with ambiguity and adept at solving complex regulatory and technical challenges.
- Inspirational and collaborative leader with a track record of building high-performing teams and fostering cross-functional alignment.
- Proactive, detail-oriented, and quality-driven, with a passion for continuous improvement and regulatory excellence.
- High integrity with an unwavering commitment to patient safety and compliance.

Reporting Structure

- Reports to: Chief Scientific Officer

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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 development and enables significant strategic and operational impact.

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

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.*

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.*