Job Description

Position Title:	Scientist II, CMC
Department	Department: Technical Operations – CMC
Reports To	Hiring Manager
Location	US Based (Remote Eligible)
Exemption Status	Status: Exempt
Job Code/Grade	A4 (Career Advanced)
Manager Level	Level

POSITION SUMMARY:

This position will play a critical role in coordinating the overall activities of the technical operations (CMC team). The Scientist will collaborate closely with internal stakeholders and Contract Development and Manufacturing Organizations (CDMO) to author and review technical documents, reports and regulatory submissions. This individual is also responsible for driving technical discussions to obtain timely resolution to ensure project timelines are not impacted.

ESSENTIAL FUNCTIONS:

- Collaborate with cross-functional teams, including Process Development, Manufacturing, Quality Assurance, Supply, and Regulatory Affairs, ensure activities are aligned with project timelines and overall business objectives.
- Analyze data from PC/PPQ studies and generate comprehensive reports, summarize key findings, conclusion and author sections of regulatory filings.
- Technical Expertise: Demonstrated proficiency in broad technical topics related to drug substance and drug product manufacturing, analytical methods, comparability assessments and regulatory requirements (e.g., FDA, ICH).
- Provide technical support and troubleshooting expertise to ensure successful execution of PC/PPQ protocols and adherence to regulatory requirements.
- Stay abreast of industry best practices, regulatory guidelines, and emerging trends in process characterization and performance qualification through literature review, participation in scientific conferences, and collaboration with external experts.
- Collaboration: Ability to collaborate effectively with cross-functional teams and external partners to achieve project goals and drive continuous improvement initiatives.
- Regulatory Compliance: Understanding of cGMP regulations and guidelines governing pharmaceutical manufacturing processes, particularly related to process validation and qualification activities.
- Analytical Skills: Strong analytical and problem-solving skills, with experience in analyzing complex data sets
- Communication: Excellent written and verbal communication skills, with the ability to convey technical information clearly and concisely to diverse audiences.

COMPETENCIES:

The following competencies describe the desired behaviors, skills, and abilities that will facilitate success at CG Oncology in this role:

1. COMMUNICATION – Expresses ideas clearly and constructively (written and spoken, upward and downward, one-on-one and with groups).

2. COLLABORATION – Is politically savvy and able to be a collaborative team player who is also an independent thinker; ability to develop a strong point of view combined with the openness to evolving that view based on new data and analysis. Tactfully navigate scientific, procedural, and cultural differences and competing concerns to maintain productive relationships to work proactively with others to streamline work and achieve mutual goals timely. Excels in a fast-paced, high-growth company environment with minimal direction and a high-degree of independence and able to adjust workload based on changing priorities.

4. PROFESSIONALISM – Treats others with respect; abides by the institutional and cultural values; displays a positive and cooperative attitude; adheres to the standards of conduct and compliance policies. Able to present oneself in a professional manner displaying executive presence, approachability, confidence, and credibility.

5. RESILIENCE – Must be resilient and able to manage around constraints and challenges to develop solutions that will involve establishing consensus from parties subject to different international regulatory standards.

6. TECHNICAL ACUMEN – Demonstrates a strong understanding of Clinical Research Operations, and Structure of CMC, key terms, processes, compliance, and timelines as they relate to advancing Biotechnology research through the pre-clinical to clinical phases. Demonstrable understanding of FDA/ICH guidelines and industry standard practices regarding clinical trial management.

7. CULTURAL ACUMEN – Demonstrates understanding of diverse cultures to facilitate and effectively communicate, collaborate, and advance the scientific process in a balanced and compliant manner.

9. MANAGEMENT/TEAMWORK – Balances team and individual responsibilities; gives and welcomes feedback; contributes to building a positive team spirit; puts success of team above own interests; supports everyone's efforts to succeed. Contributes to building a positive team spirit; shares expertise with others.

PROFESSIONAL QUALIFICATIONS

Minimum Education:	Education: Bachelor's degree in Chemical Engineering, Pharmaceutical Sciences, or related field.
Minimum Experience:	Minimum Experience • Three to five years of relevant experience in process development, manufacturing or related areas within the biotechnology industry. • Technical Proficiency: Proficiency in Microsoft Office suite.
Other Requirements:	Minimum requirements • Regulatory Knowledge: Familiarity with FDA and ICH guidelines for process validation and qualification activities

Preferred Education:	Education (BSc. Or higher)
Pref. Certification/Licensure:	
Software	MS Office, required. Windows, required. Electronic/cloud-based documentation and filing systems
Communication	English languages (verbal, written and speaking ability) Excellent verbal communication and telephone skills Excellent written communication skills

Employee: _____ Date: _____

Dept. Head/Hiring Manager _____ Date: _____