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| **JOB TITLE:** | Associate Director/Director Quality Control and Analytical Development | **REPORTS TO:** | VP Analytical Development and Quality Control |
| **DEPARTMENT:** | Manufacturing/Quality | **LOCATION:** | Irvine, CA (Remote possibility) |
| **EFFECTIVE:** | Sept. 24, 2021 | **TRAVEL:** | Occasional |

Founded in 2010, CG Oncology is a privately-held, clinical-stage biopharmaceutical company focused on the research, acquisition, and development of oncolytic immunotherapies to combat cancer. We employ a capital-efficient operating model to achieve expedited product approval. Our strategy is centered on providing patients with new and impactful therapies. Our lead proprietary agent, CG0070, has the potential to deliver safe and effective cancer care alone and in combination with other immunotherapies. CG0070 has been shown to be a safe agent in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) and we are exploring further types of cancer in clinical studies. At CG Oncology, we aim to take the next evolutionary step in delivering innovative cancer care to millions of patients in need worldwide.

CG Oncology is seeking world-class, high-performing professionals who desire great opportunities and career growth while providing exceptional contributions to the organization. The Company is quickly growing, with a huge amount of potential and opportunity for personal growth and development. The Company has recruited an exceptional leadership team with vast experience and demonstrated success in research, drug development, manufacturing, and operations while surrounding itself with an accomplished board of directors and advisors with deep experience in investment in the healthcare sector and making impactful scientific contributions in pharmaceutical research and development, specifically in oncolytic immunotherapies.

**Join the CG Oncology Team**

We thrive on innovation, action, and *results*. As science evolves, so do we – staying in the forefront of new research and advancements in new therapies to treat and ultimately cure cancer. We're on a mission to make an impact in developing breakthrough therapies that will benefit millions of patients, caregivers, and families impacted by cancer.

You will be an integral member of a cross-functional team that consists of highly motivated professionals with deep knowledge and experience in regulatory, drug development, drug safety, manufacturing, and operations. The team is responsible for the successful execution of the Company's strategic objectives including several clinical studies in a cost-effective, safe, and compliant manner.

**Position Summary**

CG Oncology is seeking an experienced Associate Director/Director of Quality Control and Analytical Development to provide technical and managerial oversight of external quality control operations and analytical method development. Responsibilities include managing external release and stability testing, reference materials and performance monitoring. The position also includes oversight of

external method development, transfer, qualification/validation and product characterization of CG Oncology's pipeline products.

This position will be an integral part of a small, highly competent and dynamic CMC drug development organization and will frequently interact with other functions within CG Oncology including quality assurance, regulatory affairs, project management, preclinical and preclinical development. This position allows working from a remote location.

**Responsibilities**

- Oversee and manage external QC testing of DS and DP
- Review and approve test methods and records for release and stability testing
- Author, review and approve GMP relevant documentation as they relate to validation, reference materials, transfer, comparability studies, specifications and others
- Lead investigations at external sites related to OOS/OOT, deviations, and unexpected analytical results.
- Direct external method development and product characterization

**Knowledge and Skills**

- Technical understanding of methodologies and analytical technologies to analyze viral products including cell-based potency methods, PCR, HPLC, ELISA and other modern analytical technologies.
- Profound understanding of data analysis including statistical principles
- Excellent organizational skills, analytical, able to implement structure in a highly dynamic environment
- Self-motivated, independent and "do-what-it-takes" attitude
- Highly developed communication skills to build relationships within CG Oncology, and corporate partners

**Requirements**

- MS or PhD in Chemistry, Biochemistry, or other related field with at least 8 years (Assoc Dir) or 12 years (Director) of industry experience in QC and/or analytical development for biologics

**To Apply:**

Imagine a career where your passion for science can result in the direct impact of people's health and well-being. Immerse yourself in a culture that is committed to improving patients' lives and the caregivers and families surrounding them. Discover what it's like to be a part of a team that is fuelled by innovation and a relentless pursuit in developing breakthrough therapies for cancer patients.

If you think you have the right skills and experience, and a passion for science, we invite you to apply at: careers@cgoncology.com. In the e-mail subject line, please indicate the position title: AD/DIR QC & Analytical Development**.**

We thank all applicants for their interest, however, only those selected will be invited for an interview.