**Last updated: 02/10/2022**

**Job Title: QC Scientist/Sr. Scientist**

**Job Summary:**

Cellular Biomedicine Group Inc. (CBMG) is a wholly owned subsidiary of CBMG Holdings. We develop proprietary cell therapies for the treatment of cancer and degenerative diseases. CBMG operates a state-of-the-art facility in Rockville, Maryland with five GMP rooms in order to augment its global research and development capabilities and to support clinical development of multiple cell therapy platform technologies in the US.

Cellular Biomedicine Group (CBMG) is a biopharmaceutical company focusing on the development of novel cancer immunotherapy products including CAR-T, TCR-T, and tumor Infiltrating lymphocytes (TIL) cells. Join CBMG’s enthusiastic and collaborative efforts by contributing to the overall success of our novel cell therapy approach. We seek a highly motivated and independent Scientist/Senior Scientist to join our QC team to support our newly established GMP facility in Rockville, Maryland for the commercialization of our multiple-stage cell therapy products. This includes performing analytical method development, method transfer, method validation/qualification, in-process control testing, product release and stability testing, and data review and trending, etc., ensuring cGMP compliance of facility and environment monitoring for clinical production.

**Responsibilities and Duties:**

* Support the GMP compliant lab quality control procedures in Maryland GMP facility.
* Develop extended product characterization methods, including but not limited to product safety, identity, impurities, heterogeneity, and potency, etc.
* Execute the Tech Transfer of analytical testing within different functions of CBMG, or from and to other parties.
* Develop and compile complete suite of analytical method documentation such as test procedures, SOPs, development/transfer/qualification/validation protocols & reports, QC test methods/reports, and analytical sampling plans, etc.
* Perform cGMP analytical testing (pH, appearance, flow cytometry, qPCR, ELISA, cell culture and bioassays) and complete the Certificate of Analysis (CoA)
* Establish and execute the stability protocols for drug substance and drug product.
* Review executed test procedures and associated documentation for release of cell therapy products
* Manage selection criteria and justification for QC raw materials and outsourced lab services.
* Review Environmental Monitoring (EM) data periodically and draft trending analysis
* Resolve the Invalid assays, OOS/OOT issues timely with collaboration of Quality Assurance function.
* Author, review, and execute equipment validations with guidance.
* Perform other duties as required.

**Qualifications and Requirements:**

* PhD/MS in life science (biology, biochemistry, bioengineering, microbiology or equivalent) with 3+ or 5+ years (MS) of relevant industry experience.
* Strong method troubleshooting skills and scientific understanding of cellular and/or tumor immunology principles, technologies, and experimental techniques.
* Excellent analytical mindset and skills including hands on experience with analytical methods.
* Maintain accurate and detailed laboratory notebook and documentation
* Understanding of FDA, EMA, ICH, USP, and EP guidelines and regulations associated with the quality control of biotherapeutic products is a plus.
* Prior working experience in a regulated environment (GMP, GLP, etc.) is preferred
* Demonstrated ability to perform technical writing with statistical evaluations of data
* Excellent time management skills with attention to details and desire to achieve team and individual goals.

**Why You Should Join CBMG**

* Join a high growth and fast paced organization
* Defined career path and annual performance review and feedback process
* 100% company-paid Medical, Dental, Vision insurance
* Company 401K match up to 6%
* Paid holidays, sick leave, and annual leave