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

**Job Title: Sr. Manager/ Associate Director, Quality Assurance**

**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.

We are seeking a collaborative and highly motivated Associate Director of Quality Assurance in Rockville, Maryland. The candidate will develop the Quality Management System and oversee the day-to-day quality operations.

**Responsibilities and Duties:**

* Establish and maintain policies and procedures for GMP Quality Systems that are compliant with US FDA requirements and the document control system.
* Establish and maintain the material management system and be responsible for the disposition of the raw materials and starting materials.
* Establish and maintain change control, deviation management, and CAPA procedure.
* Establish and maintain GMP personnel training and qualification procedure.
* Establish and maintain facility commission and qualification procedures.
* Maintain the validation master plan and oversee the validation and qualification activities.
* Responsible for product disposition such as batch record review, testing record review, resolution of deviations or completion of change requests.
* Oversee contract manufacturing organizations and contract test laboratories on their relevant production and testing activities.
* Ensure the data integrity of GMP activities.
* Initiate and maintain Quality Assurance Agreements with contractors
* Host audits from collaborators or inspections from regulatory bodies.
* Coordinate and perform audits on contract manufacturing organizations or relevant clinical sites.
* Perform other duties as assigned.

**Qualifications and Requirements:**

* **Senior Manager**: Bachelor’s degree in life science or a related scientific discipline, with at least 8-10 years’ experience in Quality Assurance roles
* **Associate Director**: Bachelor’s degree (Ph.D. preferred) in life science or a related scientific discipline, with 10+ years’ experience in Quality Assurance roles
* Working knowledge of cGMP principles with respect to FDA regulations
* Workable knowledge with aseptic processing regulations and guidelines
* Broad knowledge of phase appropriate Quality System implementation and maintenance
* Extensive knowledge and experience with a risk-based approach to Quality System implementation
* Previous experience working with clinical-stage biological products such as antibodies, vaccines or recombinant antibodies.
* Strong analysis and problem-solving skills.
* Ability to work in a dynamic, fast-paced environment with shifting priorities
* Ability to work collaboratively with teams and collaborators

**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