**Last updated: 03/09/2022**

**Job Title: Specialist or Senior Specialist, Quality Assurance**

**Job Summary:**

Cellular Biomedicine Group Inc. (CBMG) is a biopharmaceutical company focused on the development of novel cancer immunotherapy products. Our core technology involves CAR-T product, TCR-T products, and tumor Infiltrating lymphocytes (TIL), for the treatment of advanced solid and hematological malignancies.

We are seeking a collaborative and highly motivated Specialist or Senior Specialist of Quality Assurance in Rockville, Maryland. The candidate will be involved in the development the Quality Management System and oversight the day-to-day quality operations.

**Responsibilities and Duties:**

* Responsible for the initiation, revision, distribution, and version control of documents following GDP requirements.
* Assist in reviewing the documents, including manufacturing Production Records, testing record, and validation protocols and reports
* Responsible for the management and control of critical materials and starting materials.
* Responsible for the training and qualification of personnel.
* Assist in compiling and verifying all batch related documents into a Final Product lot disposition package
* Perform quality investigations of manufacturing Deviations, GMP and Quality System issues, non-conforming materials, and CAPA
* Provide Quality Assurance support resolving material, in-process product, final product, environmental, facility and equipment manufacturing issues
* Participate in the management of day-to-day activities for the initiation, tracking, and closure of non-conformances and CAPA activities
* Participate in the validation tasks and the internal audits of the quality management system
* Review equipment and facility technical and investigation reports
* Participated in quality on site activities.
* Assist in reviewing proposed changes to systems, procedures, methods, and submissions to regulatory agencies
* Perform other duties as required.
* Perform other duties that may be assigned.

**Qualifications and Requirements:**

* Bachelor’s Degree in life science or a related scientific discipline, 1-3 years’ experience in Quality Assurance roles
* Working knowledge of cGMP principles with respect to FDA regulations
* Workable knowledge with aseptic processing regulations and guidelines
* Sufficient knowledge of phase appropriate Quality System implementation and maintenance
* Knowledge and experience with risk-based approach to Quality System implementation
* Previous experience working with clinical stage biological products such as antibodies, vaccines or recombinant antibodies.
* Strong communication and coordination skills, good language skills and the ability to analyze and solve problems with a positive work attitude.
* Ability to work in a dynamic, fast paced environment with shifting priorities
* Ability to work collaboratively with teams and collaborators

**Preferred Qualifications:**

* Self-starter with superior analysis and problem-solving skills ranging from simple to sophisticated situations.
* Be proficient in MS Office suite.
* Demonstrates proficiency in current Good Manufacturing Practices (GMPs).
* Possess good communications skills to explain information and influence others
* Must have a strong work ethic and demonstrate dependability and timeliness.
* Have a high energy level and a positive outlook coupled with the requisite “can do” attitude.

**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