UNIVERSITY OF SOUTHERN CALIFORNIA

cGMP Quality Control Specialist

Job Code: 188013

OT Eligible: **No**

Comp Approval: **3/23/2021**

JOB SUMMARY:

Responsible for designing, developing, evaluating, and implementing quality control testing, assays, and procedures for materials and final cell therapy products manufacturing. Ensures consistency with current Good Manufacturing Practice (cGMP) principles.

JOB ACCOUNTABILITIES:

*E/M/NA	% TIME	
_____	_____	Supports cGMP manufacturing operations with responsibility for quality control. Performs cGMP batch release testing to ensure pharmaceuticals and biopharmaceuticals are of highest possible quality before being applied to patients. Writes and reviews qualifications (e.g., installation, operation, performance), facility operation plans and reports, standard operating procedures, and batch records as required. Completes batch record documentation, all appropriate equipment log entries, and cGMP documentation.
_____	_____	Operates instrumentation needed for cell and gene therapy manufacturing (e.g., cell counters, bioreactors, centrifuges, biological safety cabinets). Assists in technology transfer of manufacturing processes from pre-clinical into cGMP environment.
_____	_____	Provides verification of facility operations and equipment and advanced problem solving, troubleshooting, and consultation support, as needed. Supervises and directs junior staff to achieve project goals. Serves as a resource to cGMP facility management in identifying and assessing the appropriate complement of resources and support needed to successfully implement and execute projects.
_____	_____	Maintains confidentiality for patient identification, specimen labeling and specimen verification during batch testing. Performs duties in a clean room environment, when needed and while fully gowned (e.g., mask, coverall, gloves), following cGMP guidelines and using aseptic techniques. Works with senior staff to ensure facilities' compliance with all applicable regulations.
_____	_____	Attends routine meetings with management team for progress reports on projects, facility needs, and discussion of any other required items. Improves current methods and evaluates innovative techniques in quality control testing for cell therapy and biologics.
_____	_____	Promotes an environment that fosters inclusive relationships and creates unbiased opportunities for contributions through ideas, words, and actions that uphold principles of the USC Code of Ethics.
		Performs other related duties as assigned or requested. The university reserves the right to add or change duties at any time.

***Select E (ESSENTIAL), M (MARGINAL) or NA (NON-APPLICABLE) to denote importance of each job function to position.**

EMERGENCY RESPONSE/RECOVERY:

Essential: ☐ No

☐ Yes In the event of an emergency, the employee holding this position is required to "report to duty" in accordance with the university's Emergency Operations Plan and/or the employee's department's emergency response and/or recovery plans. Familiarity with those plans and regular training to implement those plans is required. During or immediately following an emergency, the employee will be notified to assist in the emergency response efforts, and mobilize other staff members if needed.

JOB QUALIFICATIONS:

Minimum Education:

Bachelor's degree

Minimum Experience:

3 years

Minimum Field of Expertise:

Bachelor's degree in a scientific discipline (e.g., pharmaceutical, biologics). Three years' experience in cellular or biological manufacturing with quality control responsibilities. Demonstrated knowledge base with Good Manufacturing Practices (e.g., cGMPs, GLPs, GDPs). Experience with standard operating procedures in a cGMP laboratory setting. Demonstrated ability to work as an individual contributor and in a dynamic team environment. Excellent written and oral communication skills.

Preferred Education:

Master's degree

Preferred Experience:

5 years

Preferred Field of Expertise:

Master's degree or higher in biotechnology or closely related field. Demonstrated knowledge of all aspects of biotechnology and cell therapy. Demonstrated passion for solving complex scientific issues. Experience with Food and Drug Administration regulations and clinical trials. Extensive leadership experience.

Supervises: Level:

May lead one or more employees performing similar work.

SIGNATURES:

Employee: _____ **Date:** _____

Supervisor: _____ **Date:** _____

The above statements are intended to describe the general nature and level of work being performed. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of personnel so classified.

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