UNIVERSITY OF SOUTHERN CALIFORNIA

cGMP Core Operator

Job Code: 188017

OT Eligible: **No**

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

JOB SUMMARY:

Supports daily manufacturing operations in current Good Manufacturing Practice (cGMP) facilities. Maintains materials, gowning, cleaning supplies, and consumable supplies, manages manufacturing waste streams, cleans equipment, oversees documentation, and supports in other manufacturing duties as required.

JOB ACCOUNTABILITIES:

*E/M/NA	% TIME	
_____	_____	Performs all product manufacturing duties in cGMP facilities, adhering to all applicable gowning and safety requirements. Prepares and properly stores all incoming, intermediate and final products. Performs quality control for incoming, in-process and final products. Generates batch records, chain of custody forms, certificates of analysis and other records. Maintains complete documentation throughout the manufacturing process.
_____	_____	Orders cGMP facility equipment and supplies. Develops an inventory system for ongoing supplies and orders. Supports senior facility staff in maintaining cGMP budgets to ensure efficient use of equipment and materials. Establishes preventative maintenance schedule routines, and designs forms for maintaining documentation of equipment maintenance.
_____	_____	Acts as technical consultant to clinicians and researchers, providing technical assistance within the facility as necessary. Develops, implements and documents standard operating procedures, making updates as necessary. Instructs and oversees cGMP technicians and instructs graduate students and post-doctoral fellows in proper procedures within cGMP facilities. 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.
_____	_____	Applies appropriate labels to incoming and outgoing products and monitors for proper labeling and handling during manufacturing. Ensures biohazard waste is handled appropriately and that medical waste stream rules and regulations are followed. Works with management to ensure facilities' compliance with all applicable regulations.
_____	_____	Plans and organizes workflows to meet established turnaround times, dispense dates and deadlines. Attends routine meetings with management team for progress reports on projects, facility needs, and discussion of any other required items. Recommends process improvements as appropriate.
_____	_____	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 laboratory responsibilities. Demonstrated knowledge base with Good Manufacturing Practices (e.g., cGMPs, GLPs, GDPs). Extensitve 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.

The University of Southern California is an Equal Opportunity Employer