USC University of Southern California

cGMP Quality Control Specialist
Job Description

JOB INFORMATION

Job Code:	188013
Job Title:	cGMP Quality Control Specialist
FLSA Status:	Exempt
Supervisory:	May lead one or more employees performing similar work.
Job Family:	Clinical Research
Job Family Group:	USC Job Families
Management Level:	7 Individual Contributor

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 QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		Or
X		Bachelor's degree	Pharmacy	Or
X		Bachelor's degree	Biology	Or
X		Bachelor's degree	in related field(s)	
	X	Master's degree	Biotechnology	Or
	X	Master's degree	in related field(s)	

Additional Education

Check here if experience may substitute for some of the above education.

	Combined experience/education as substitute for minimum education

Work Experience

Req	*Pref*	*Work Experience*	*Experience Level*	
X		3 years		

Additional Work Experience

Check here if education may substitute for some of the above work experience.

	Combined experience/education as substitute for minimum work experience

Knowledge, Skills and Abilities

Req	*Pref*	*Functional Skills*
X		Demonstrated knowledge base with Good Manufacturing Practices (e.g., cGMPs, GLPs, GDPs).

Knowledge, Skills and Abilities

Req	Pref	Functional Skills
X		Experience with standard operating procedures in a cGMP laboratory setting.
X		Demonstrated ability to work as an individual contributor and in a dynamic team environment.
X		Excellent written and oral communication skills.
	X	Demonstrated knowledge of all aspects of biotechnology and cell therapy.
	X	Demonstrated passion for solving complex scientific issues.
	X	Experience with Food and Drug Administration regulations and clinical trials.
	X	Extensive leadership experience.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
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.				

Other Requirements

Essential:	Emergency Response/Recovery	Essential:	Mandated Reporter
	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.		A mandated reporter who in his or her professional capacity has knowledge of, or reasonably suspects a person who is under the age of 18 years, elderly, or a dependent adult has been the victim of abuse or neglect must report the suspected incident. The reporter must contact a designated agency immediately or as soon as practically possible by telephone or in writing within 36 hours. By virtue of the associated job duties, this position qualifies as a mandated reporter as required by state law and USC’s policy at: https://policy.usc.edu/mandated-reporters/

Campus Security Authority (CSA)	*Essential:*
By virtue of the associated job duties, this position qualifies as a Campus Security Authority as required by law and USC's policy at: https://dps.usc.edu/alerts/clery/	

ACKNOWLEDGMENTS

The above statements reflect the essential and non-essential functions as necessary to describe the principle contents of the job. They are not intended to be a complete statement of all work requirements or duties that may be required of the position. I understand that I may be asked to perform other duties as assigned. USC reserves the right to add or change duties at any time.

The University of Southern California is an Equal Opportunity Employer. USC prohibits discrimination on any basis protected under federal, state, or local law, regulation, or ordinance or university policies. All employment decisions are based on individual qualifications and business need.

I acknowledge receipt of this job description and its associated physical requirements. I have read and understand the job description and job requirements and agree to abide by their contents. I realize that duties may be requested of me that are not specifically stated herein. I understand that I will be expected to adjust to potential fluctuations in work volume. I understand that, if I have any questions about the essential functions or expectations of my position, my supervisor and/or HR partner are available to discuss them with me.

_____	_____	_____
Print Employee Name	Signature	Date
_____	_____	_____
Print Manager Name	Signature	Date

This job description describes the general nature and level of work required by the position. It is not intended to be an all-inclusive list of qualifications, skills,
duties, responsibilities or working conditions of the job. The job description is subject to change with or without notice, and Management reserves the right to add, modify or remove any qualification or duty. Nothing in this job description changes the existing at-will employment relationship between the university and the employee occupying the position.