cGMP Quality Assurance Specialist
Job Description

JOB INFORMATION

Job Code:	188009
Job Title:	cGMP Quality Assurance Specialist
FLSA Status:	Exempt
Supervisory:	Leads one or more employees performing similar work.
Job Family:	Clinical Research
Job Family Group:	USC Job Families
Management Level:	8 Individual Contributor

cGMP Quality Assurance Specialist

JOB SUMMARY

Responsible for ensuring operations quality and compliance with current Good Manufacturing Practice (cGMP) regulations. Establishes, controls, monitors and records all activities which directly/indirectly impact aspects of cell therapy product quality. Establishes a Corrective and Preventative Actions (CAPA) system that manages the response to errors, accidents, complaints and clinical trial-related adverse events. Ensures that cell therapy products have been produced within established process and release requirements.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		In
X			Pharmacy	Or
X			Biology	Or
X			in related field(s)	
	X	Master's degree		In
	X		Biotechnology	Or
	X		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	in cellular or biological manufacturing with quality assurance responsibilities.	

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).
X		Experience with and knowledge of 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 assurance (QA). Manages internal quality improvement initiatives, evaluates internal processes, and suggests, designs, and implements improvements. Provides QA support for validations, (e.g., reviewing facility operations plans, training programs, standard operating procedures) as required. Provides support with batch record documentation, all appropriate equipment log entries, and cGMP documentation.				
Manages the supplier/vendor qualification process in support of cGMP activities. Reviews and approves raw material specifications.				
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.				
Establishes and oversees self-auditing program to ensure facilities' continual compliance with relevant regulatory requirements, working with external inspectors as needed. Manages the CAPA process, ensuring remedial actions are taken and documented when test systems deviate from established performance specifications. Works with senior staff to ensure facilities' compliance with all applicable regulations.				
Assists with validation, routine performance, and process and analytical method development to support cell therapy products. Attends routine meetings with management team for progress reports on projects, facility needs, and discussion of any other required items.				
Encourages a workplace culture where all employees are valued, value others and have the opportunity to contribute through their ideas, words and actions, in accordance with 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.