USC University of Southern California

Senior Quality Control Specialist
Job Description

JOB INFORMATION

Job Code:	188014
Job Title:	Senior 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

Leads advanced quality control activities to ensure the quality and compliance of cell and gene therapy products. Independently designs, qualifies, and optimizes complex assays, overseeing multiple projects and collaborating closely with other teams. Conducts in-depth analytical testing, establishes stability programs, and creates robust sampling plans while leading audits and mentoring junior staff. Enhances QC processes and upholds regulatory standards in a dynamic, cross-functional environment.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		In
X			Biotechnology	Or
X			Chemistry	Or
X			Biochemistry	Or
X			in related field(s)	
	X	Master's degree		In
	X		Biotechnology	Or
	X		Chemistry	Or
	X		Biochemistry	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		7 years		
	X	10 years	in quality control and analytical development	

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 standard operating procedures in a 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.
	X	Experience setting and maintaining operating procedures and best practices

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	*Essential*	*Marginal*	*N/A*
Independently designs, optimizes, and fully qualifies assays for cell and gene therapy products, ensuring each method meets regulatory standards and is robust, reliable, and reproducible. Troubleshoots challenging assays and develops protocols for resolving issues. Independently trends and analyzes QC assay data to identify and implement improvements.				
Oversees and manages all QC activities across multiple concurrent projects. Leads the planning and performance of complex analytical testing on in-process materials, raw materials, and final products to ensure they meet established specifications and stringent quality criteria. Acts as the primary QC liaison to actively participate in cross-functional meetings with other departments to ensure seamless coordination in product testing and release.				
Designs and implements robust sampling plans that cover critical steps and parameters in cell and gene therapy manufacturing processes. Establishes and leads stability-testing programs to monitor the long-term quality of cell and gene therapy products. Performs investigations and develops CAPAs of analytical development and QC related deviations/incidents. Develops QC equipment qualification and validation plans whenever necessary.				
Performs real-time quality control on manufacturing batches, supports investigations related to batch failures and executes experiments that refine manufacturing-related QC processes, including environmental monitoring and contamination risk assessments. Creates and qualifies customized control and reference standards for critical assays to improve assay robustness and reproducibility.				
Takes a leadership role in internal and external audits, preparing necessary documentation and addressing QC-related queries to ensure regulatory compliance. Develops and trains new team members in assigned operations. Acts as a mentor for junior team members, providing guidance on assay design, troubleshooting, and best practices in data interpretation. Drafts and reviews policies and Standard Operating Procedures (SOPs) for QC tests and operations.				
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.