USC University of Southern California

Associate Director, cGMP
Job Description

JOB INFORMATION

Job Code:	188020
Job Title:	Associate Director, cGMP
FLSA Status:	Exempt
Supervisory:	May supervise staff, student, temporary or resource workers.
Job Family:	Clinical Research
Job Family Group:	USC Job Families
Management Level:	4 Administrator

JOB SUMMARY

Provides strategic direction that engages all employees and continuously improves quality, productivity, operations, and cost. Responsible for all aspects of operations and quality system related to Current Good Manufacturing Practice (cGMP) laboratory and ensuring cGMP project deliverables meet schedules, cost, scope, quality and safety. Oversees technology transfer activities of new projects.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Master's degree	Pharmaceutical Sciences	Or
X		Master's degree	in related field(s)	
	X	Doctorate	Biotechnology	Or
	X	Doctorate	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		4 years	of cellular or biological manufacturing experience (e.g., process development and analytical methods).	
	X	6 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		Master's degree in a scientific discipline (e.g., pharmaceutical, biologics).
X		Proven experience in leadership/management roles.
X		Demonstrated experience in academic administration and quality management.
X		Solid knowledge base in Good Manufacturing Practices (e.g., cGMPs, GLPs, GDPs), cellular and gene therapies, translational research, and the business of science.
X		Demonstrated ability to work as an individual contributor and in dynamic team environments.
X		Excellent written and oral communication skills.
	X	Doctorate in biotechnology or other related life science disciplines.
	X	Experience and knowledge of standard operating procedures in cGMP laboratory settings.
	X	Ability to drive vendor selection and engagement, manage relationships, evaluate vendor data, document test plans, and develop deployment workbooks.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Develops and implements strategies that proactively identify and mitigate risks. Establishes strategic goals and objectives for product manufacturing operations. Enhances and supports cross-functional interactions and activity prioritization. Regularly ensures compliance with all relevant regulatory requirements.				
Oversees the implementation of project plans (e.g., process and assay development and qualification), support tech transfer of processes to cGMP manufacturing and assays to QC. Develops and reviews SOPs, protocols and technical reports.				
Works closely with internal/external stakeholders to ensure project success and competition. Coaches and develops staff and coordinates departmental hiring/staffing plans. Identifies improvement opportunities to optimize workflows and eliminate inefficiencies. Establishes metrics and reports on the state of cGMP operations to senior management.				
Participates in vendor management and qualification visits as needed. Attends regular meetings with management discussing progress reports, facility needs and other required items.				
Ensures timely delivery of project goals and creates periodic progress reports summarizing status and potential risks. Assists with design and delivery of training courses. Stays current with new/emerging technologies and approaches, leveraging the latest industry knowledge to facilitate opportunities for innovation and continuous improvement.				
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. Creates staff development opportunities, reads and contributes to journals, and participates in professional organizations, meetings, conferences, seminars, and training courses.				

Other Requirements

Essential:	Emergency Response/Recovery	Essential:	Mandated Reporter
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.		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.