USC University of Southern California

cGMP Manufacturing Specialist
Job Description

JOB INFORMATION

Job Code:	188001
Job Title:	cGMP Manufacturing 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

Manufactures biologics and drugs for cell and gene therapy of internal/external users in the university’s current Good Manufacturing Practices (cGMP) facilities. Researches and develops methods for improving manufacturing cell therapy processes. Works with product pipelines at various stages of development, initiating and generating ideas based on research findings. Assists in fostering collaborative translational research environments. Actively participates in establishing, implementing and maintaining the cell therapy program’s mission and vision.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Bachelor's degree		
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	in cellular or biological manufacturing and with process development and analytical methods	

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		Familiarity with manufacturing methods and procedures.
X		Demonstrated knowledge base with Good Manufacturing Practices (e.g., cGMPs, GLPs, GDPs).
X		Experience applying sound technical judgement to a variety of manufacturing scenarios. Excellent planning and time management abilities.
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
Creates technical reports and specifications, maintaining appropriate records. Drafts, writes, and edits scientific reports, papers, journal articles, and abstracts. Assists in preparing grant applications.				
Establishes production processes, modifying raw materials, components, and process parameters as necessary to ensure quality. Devises, validates and/or refines processes to optimize the manufacturing process. Improves yields and reduces costs by investigating alternative machinery and materials and addressing quality and efficiency issues in bottleneck areas. Advises on equipment modifications to optimize new product development.				
Implements appropriate and effective regulatory strategies. Participates in all relevant internal/external audits and inspections, maintaining set quality standards and ensuring the program meets GMP requirements.				
Reviews Chemistry, Manufacturing, and Controls (CMC) information and any relevant clinical/non-clinical documentation. Assists in completing and coordinating successful submissions of Investigational New Drug (IND) applications. Develops formulas, assays, and specifications to ensure compliance with finished product release criteria.				
Stays current with developments in the field and presents information on research and program work at appropriate meetings, journal clubs, and seminars. Helps develop new courses at the undergraduate and graduate level.				
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.