

**SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING
TECHNICAL SKILLS & COMPETENCIES (TSC) REFERENCE DOCUMENT**

TSC Category	Production					
TSC	Cell Culture					
TSC Description	Maintain both microbial and mammalian cell cultures as pure cultures during the upstream stages of production					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
			BPM-OPR-3003-1.1	BPM-OPR-4003-1.1	BPM-OPR-5003-1.1	
			Implement aseptic cell culture techniques to maintain cell cultures in a pure state during production	Guide cell culture activities and oversee implementation	Advise on optimal cell culture processes, integrating manufacturing demands and other production processes	
Knowledge			<ul style="list-style-type: none"> • Current Good Manufacturing Practices (CGMPs) • Principles of microbiology and biochemistry • Principles of cell banks • Microbiological techniques and aseptic preparation • Principles of mammalian cell culture processes • Virus classification, entry into cells, replication and immune responses • Types of viral vaccines and antiviral drugs • Viral inactivation techniques in production processes • Viral clearance studies 	<ul style="list-style-type: none"> • Current Good Manufacturing Practices (CGMPs) • Principles of microbiology and biochemistry • Types of cell culture techniques • Procedures to verify safety and quality conditions during cell culture operations • Types and indicators of hazards or abnormal conditions during operations 	<ul style="list-style-type: none"> • End-to-end processes, systems and equipment used in biologics production • Organisation's requirements related to the production of biologics products • Pros, cons and key considerations of different cell culture processes • Industry best practices in the development and maintenance of cell cultures during upstream processes • Technical and environmental factors that impact the outcomes of cell culture activities • Industry standards of risk management in biopharmaceuticals manufacturing 	
Abilities			<ul style="list-style-type: none"> • Follow aseptic techniques when working with biological materials • Prepare and examine microbial slides 	<ul style="list-style-type: none"> • Select media, materials and equipment for cell culture processes • Define process steps for cell culture maintenance during the upstream stages of production 	<ul style="list-style-type: none"> • Integrate cell culture activities with other systems and processes in the biopharmaceuticals manufacturing facilities 	

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			<ul style="list-style-type: none"> • Perform bacterial Gram stains • Prepare pour-plates and shake-flask cultures • Isolate colonies and maintain pure cultures in accordance with Standard Operating Procedures (SOPs) • Extrapolate plate counts to obtain the correct colony-forming-units (CFUs) in starting samples • Determine growth of suspension cells and anchorage-dependent cells on microcarriers • Conduct plaque assays to verify and maintain viral clearance barriers 	<ul style="list-style-type: none"> • Align cell culture operations to relevant regulations, codes, guidelines and Quality Assurance (QA) procedures • Communicate performance parameters and propagation targets for cell culture activities • Maintain oversight of cell culture activities • Record speed and yield of cell propagation • Identify and mitigate hazards associated with the samples, preparation methods, reagents and equipment 	<ul style="list-style-type: none"> • Develop internal guidelines and standards for cell culture operations in line with Current Good Manufacturing Practices (CGMPs) • Determine performance parameters for cell cultivation activities • Troubleshoot technical issues in cell culture operations • Assess process performance to identify opportunities for optimisation • Establish processes and mechanisms to manage risks and hazards associated with cell cultures 	
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