

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

<b>TSC Category</b>	Production					
<b>TSC</b>	Bioreactor Operation and Control					
<b>TSC Description</b>	Operate bioreactors in biopharmaceuticals manufacturing facilities					
<b>TSC Proficiency Description</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Level 4</b>	<b>Level 5</b>	<b>Level 6</b>
			<b>BPM-OPR-3002-1.1</b>	<b>BPM-OPR-4002-1.1</b>		
			Implement procedures for operating bioreactors	Verify conditions and operations of bioreactors and perform troubleshooting		
<b>Knowledge</b>			<ul style="list-style-type: none"> <li>• Bioreactor designs and applications</li> <li>• Principles of microbiology and biochemistry</li> <li>• Principles of fluid flow, heat transfer and mass transfer</li> <li>• Critical process parameters for operating bioreactors</li> <li>• Methods of monitoring and controlling cell culture conditions in bioreactors</li> <li>• Sterilisation requirements for cell culture media and bioreactor systems</li> <li>• Requirements of inocula for cell culture processes</li> <li>• Fundamentals of batch, continuous and fed-batch cell culture processes</li> <li>• Safety precautions associated with bioreactor operations and waste disposal</li> <li>• Methods for product recovery from cell culture processes</li> </ul>	<ul style="list-style-type: none"> <li>• Optimal operating conditions for bioreactors</li> <li>• Procedures to verify safety and quality conditions during equipment use and manufacturing operations</li> <li>• Types and indicators of hazards or abnormal conditions involving processes, equipment and materials during operations</li> <li>• Troubleshooting methods and equipment- or process-adjustment principles to restore optimal operating conditions</li> <li>• Risk assessment and mitigation techniques</li> </ul>		
<b>Abilities</b>			<ul style="list-style-type: none"> <li>• Set up bioreactors and single-use bioreactor bags by calibrating and</li> </ul>	<ul style="list-style-type: none"> <li>• Identify the cell culture process requirements and objectives</li> </ul>		

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			<p>installing pH probe, Dissolved Oxygen (DO) probe, and inlet and exit gas filters</p> <ul style="list-style-type: none"> <li>• Load culture medium into bioreactors</li> <li>• Test agitation and aeration, temperature controller and pH controller</li> <li>• Sterilise bioreactors, equipment, feed containers and reagent solutions before and after use</li> <li>• Perform bioreactor inoculation</li> <li>• Notify the authorised personnel where bioreactor operations cannot be carried out</li> <li>• Extract samples from bioreactors to measure cell density, viability and concentration</li> <li>• Carry out culture harvesting and dispose sterilised biohazard wasters</li> <li>• Prepare bioreactors for next culture operations</li> <li>• Complete log and batch sheets</li> </ul>	<ul style="list-style-type: none"> <li>• Implement Standard Operating Procedures (SOPs) for bioreactor operations</li> <li>• Inspect and verify the conditions and operations of bioreactor components</li> <li>• Oversee bioreactor preparation and start-up</li> <li>• Oversee and direct changes to critical parameters to adjust or restore bioreactors to optimal functioning</li> <li>• Review batch sample testing outcomes to verify product quality</li> <li>• Identify defects or faults in equipment parts or operations</li> <li>• Conduct root cause analysis</li> <li>• Mitigate risks associated with identified hazards relating to bioreactor operations</li> </ul>		
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