

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

<b>TSC Category</b>	Process Development/Manufacturing Science and Technology					
<b>TSC</b>	Process Optimisation					
<b>TSC Description</b>	Analyse biopharmaceuticals manufacturing processes and identify adjustments that will reduce costs of manufacturing and increase quality, throughput and efficiency					
<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-PST-3011-1.1</b>	<b>BPM-PST-4011-1.1</b>	<b>BPM-PST-5011-1.1</b>	
			Analyse process and equipment performance data to identify sub-optimal performance	Facilitate process optimisation by investigating causes of sub-optimal performance and identifying opportunities for improvements	Lead process optimisation to support the achievement of operational and manufacturing targets	
<b>Knowledge</b>			<ul style="list-style-type: none"> <li>• Biopharmaceuticals manufacturing processes</li> <li>• Current Good Manufacturing Practices (CGMPs)</li> <li>• Indicators of process and equipment performance</li> <li>• Methods of analysing data</li> <li>• Manufacturing facilities performance capacity</li> <li>• Optimal conditions of manufacturing equipment</li> <li>• Operational and manufacturing targets</li> <li>• Resource and utility requirements of processes and related equipment</li> <li>• Manufacturing throughputs and efficiency targets</li> <li>• Health issues, safety procedures and quality system guidelines which must be followed</li> </ul>	<ul style="list-style-type: none"> <li>• Applications of process automation and control systems</li> <li>• Process trouble shooting and diagnosis</li> <li>• Throughput and efficiency analysis</li> <li>• Continuous improvement tools and techniques</li> <li>• Methods of increasing efficiency in manufacturing processes</li> <li>• Relative contributions of organisational, social, cognitive, perceptual, environmental and industrial factors to employees performing manufacturing processes</li> <li>• Design principles for workplace infrastructure aids, controls, displays and instrumentation that support processes</li> </ul>	<ul style="list-style-type: none"> <li>• Operational and manufacturing targets</li> <li>• Competitive systems and practices</li> <li>• Factors that make up the total costs of manufacturing processes</li> <li>• Equipment operating capacity, process capability and other performance indicators and targets</li> <li>• Business strategies and objectives</li> </ul>	
<b>Abilities</b>			<ul style="list-style-type: none"> <li>• Verify accuracy and reliability of process and</li> </ul>	<ul style="list-style-type: none"> <li>• Review process maps and workflows to understand the purpose</li> </ul>	<ul style="list-style-type: none"> <li>• Devise criteria to assess process performance</li> </ul>	

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			<p>equipment performance data</p> <ul style="list-style-type: none"> <li>• Gather inputs from users on their requirements, needs as well as interfacing and ergonomic preferences throughout manufacturing processes</li> <li>• Analyse process and equipment performance data</li> <li>• Assess process and equipment performance information against agreed criteria</li> <li>• Highlight sub-optimal performance occurrences and patterns</li> <li>• Report findings from process analysis</li> <li>• Propose suggestions for assistive devices, equipment, aids or facilities changes which could enhance compatibility between persons and environments and optimise manufacturing processes</li> <li>• Revise Standard Operating Procedures (SOPs) upon the introduction of new processes, technologies or equipment</li> <li>• Implement proposed process optimisation solutions with the manufacturing department</li> </ul>	<p>and scope of each step in order to streamline and optimise the manufacturing processes</p> <ul style="list-style-type: none"> <li>• Conduct periodic reviews of current Standard Operating Procedures (SOPs)</li> <li>• Review process maps and workflows to identify potential blockages or bottlenecks</li> <li>• Review process and equipment performance analysis</li> <li>• Investigate causes of sub-optimal processes and equipment performance</li> <li>• Identify opportunities to remove or minimise causes of sub-optimal process performance</li> <li>• Devise and implement solutions to address suboptimal products, gaps, inefficiencies or inefficacies of process controls</li> <li>• Develop proofs of concepts, procedural storyboards, prototypes and simulations of new or enhanced process designs</li> <li>• Facilitate pilot test runs and report results</li> <li>• Monitor implementation of process optimisation plans to detect changes in throughput and efficiency</li> </ul>	<ul style="list-style-type: none"> <li>• Evaluate opportunities for process optimisation</li> <li>• Develop solutions to optimise the manufacturing processes in order to achieve pre-established manufacturing targets</li> <li>• Build business cases for implementation of proposed solutions</li> <li>• Negotiate with relevant stakeholders to secure required resources to support process optimisation solutions</li> <li>• Initiate pilot test runs of proposed optimisation solutions prior to full scale roll-out</li> <li>• Ensure compliance of proposed optimisation interventions with manufacturing Quality and Health, Safety and Environment (HSE) requirements</li> <li>• Lead change initiatives that will optimise manufacturing performance</li> <li>• Formulate implementation strategies to support deployment of solutions</li> <li>• Evaluate success of process optimisation interventions</li> </ul>	
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