

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

TSC Category	Engineering and Maintenance					
TSC	Automated Equipment and Control Systems Configuration					
TSC Description	Configure automated equipment and control systems to support biopharmaceuticals manufacturing processes					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
			BPM-ENM-3001-1.1	BPM-ENM-4001-1.1	BPM-ENM-5001-1.1	
			Configure automated manufacturing equipment and control systems and support testing activities	Develop configuration plans and acceptance criteria for automated manufacturing equipment and control systems and oversee equipment set-up	Optimise the functions of automated manufacturing equipment and control systems	
<b>Knowledge</b>			<ul style="list-style-type: none"> <li>Principles of automation, automatic control systems and automatic manufacturing technologies</li> <li>Types and features of automated equipment used in a biopharmaceuticals manufacturing facility</li> <li>Manufacturing process steps</li> <li>Fundamental concepts of software programming</li> <li>Types and characteristics of automation input devices</li> <li>Interpretation of electrical symbols and schematic diagrams</li> <li>Analysis of power supply voltages</li> <li>Principles of electrical networking</li> <li>Current Good Manufacturing Practices (CGMPs)</li> </ul>	<ul style="list-style-type: none"> <li>Procedures of configuring hydraulic and pneumatic automated systems</li> <li>Principles of automatic control systems engineering</li> <li>Concepts of contingency planning</li> <li>Principles of interaction between electronic and mechanical components</li> <li>Types and principles of electrical instrumentation</li> <li>Programming techniques and languages</li> <li>Root cause analysis</li> <li>Principles of cyber-security</li> </ul>	<ul style="list-style-type: none"> <li>Advanced principles of automated systems configuration</li> <li>Methods of defining automated equipment and control systems performance parameters</li> <li>Indicators of optimal functioning of automated manufacturing equipment and control systems</li> <li>Methods of optimising automated equipment and control systems</li> <li>Detailed procedures of each manufacturing process</li> <li>Best practices and industry innovations in the field of coding and programming automated systems</li> </ul>	
<b>Abilities</b>			<ul style="list-style-type: none"> <li>Configure automated equipment under guidance</li> </ul>	<ul style="list-style-type: none"> <li>Interpret requirements of automated manufacturing</li> </ul>	<ul style="list-style-type: none"> <li>Establish performance parameters for new automated equipment</li> </ul>	

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			<ul style="list-style-type: none"> <li>• Test the new automated equipment to ensure adherence to technical specifications</li> <li>• Record automated equipment testing results</li> <li>• Analyse testing results and suggest configuration adjustments</li> <li>• Perform periodic preventive maintenance tasks to monitor performance of automated systems</li> <li>• Provide first line troubleshooting for malfunctioning automation equipment, systems and controls</li> </ul>	<p>equipment and control systems for the manufacturing processes</p> <ul style="list-style-type: none"> <li>• Develop configuration plans including specific acceptance criteria and data to be collected</li> <li>• Calibrate robot motors, sensors and encoders</li> <li>• Programme the automation systems to implement the control strategies</li> <li>• Identify potential hazards in using automated equipment in lieu of manpower</li> <li>• Create contingency procedures for local and remote intervention</li> <li>• Conduct test runs of new automated equipment and control systems prior to launch</li> <li>• Assess test-run results against performance parameters</li> </ul>	<p>and control systems to ensure alignment with manufacturing requirements</p> <ul style="list-style-type: none"> <li>• Optimise robot functions</li> <li>• Review configuration plans and specific acceptance criteria</li> <li>• Guide configuration of new automated manufacturing equipment and control systems</li> <li>• Review programming inputs and suggest improvement</li> </ul>	
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