

**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 Modelling					
<b>TSC Description</b>	Model manufacturing processes in order to ensure successful implementation					
<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-4009-1.1</b>	<b>BPM-PST-5009-1.1</b>	
				Analyse relationships between biopharmaceuticals manufacturing processes through the application of statistical techniques	Conceptualise design and optimisation of process operations and manufacturing facilities through the application of statistical treatments	
<b>Knowledge</b>				<ul style="list-style-type: none"> <li>• Use of statistical techniques and software</li> <li>• Data analytics</li> <li>• Multivariate analysis</li> <li>• Statistical modelling and simulation software</li> <li>• Biopharmaceuticals manufacturing process phases</li> <li>• Single-use disposable technologies and systems</li> <li>• Process inputs including labour, raw materials, equipment, utilities and other relevant resources</li> <li>• Capacity modelling</li> <li>• Concept of Quality By Design (QbD)</li> </ul>	<ul style="list-style-type: none"> <li>• Biopharmaceuticals manufacturing facilities and process designs</li> <li>• Downstream processing</li> <li>• Value stream mapping</li> <li>• Vaccine and therapy production processes</li> <li>• Continuous manufacturing</li> <li>• Multi-product facilities</li> <li>• Business implications of process simulation results and findings</li> <li>• Variables impacting production throughputs</li> </ul>	
<b>Abilities</b>				<ul style="list-style-type: none"> <li>• Apply software and statistical techniques to analyse the relationships between individual unit operations and process stages within the overall biopharmaceuticals manufacturing processes</li> <li>• Analyse processes with multiple variables</li> <li>• Model the effect of adjusting input values or</li> </ul>	<ul style="list-style-type: none"> <li>• Investigate and analyse multifaceted and/or integrated unit operations and biochemical processes</li> <li>• Facilitate the conceptual design and optimisation of process operations and manufacturing facilities</li> <li>• Determine statistical techniques and software</li> </ul>	

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				<p>operating parameters on productivity</p> <ul style="list-style-type: none"> <li>• Perform simulations to determine the demand of resources to manufacture certain products</li> <li>• Analyse the manufacturing capacity of specific processes and equipment</li> </ul>	<p>to be used for process modelling</p> <ul style="list-style-type: none"> <li>• Set parameters for process models and simulations</li> <li>• Construct process models using statistical techniques and software</li> <li>• Direct modelling of processes to identify steps and requirements to transition products from the development sites to the manufacturing sites</li> <li>• Visualise outcomes of various process design decisions using statistical simulations</li> <li>• Interpret input to output relationships represented by statistical models</li> <li>• Analyse the manufacturing capacity of integrated processes, equipment and the overall facilities</li> <li>• Present critical insights from process models, highlighting investment required versus benefits and capacity of various process alternatives</li> </ul>	
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