

**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 Analytical Technology Implementation					
<b>TSC Description</b>	Apply Process Analytical Technology to design, analyse and control manufacturing processes to enhance production efficiency and quality					
<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-3008-1.1</b>	<b>BPM-PST-4008-1.1</b>	<b>BPM-PST-5008-1.1</b>	
			Analyse Process Analytical Technology (PAT) data and outputs using quantitative, semi-quantitative and qualitative techniques	Assess operational feasibility and implement Process Analytical Technology (PAT)	Guide the application of Process Analytical Technology (PAT) and establish parameters for statistical analysis and modelling	
<b>Knowledge</b>			<ul style="list-style-type: none"> <li>Principles of biopharmaceuticals manufacturing processes</li> <li>Types of PAT tools and their applications</li> <li>Types of atline, online or inline measurements</li> <li>Types of quality and performance attributes of raw and in-process materials and processes</li> <li>User interface of PAT tools</li> <li>Data validation techniques</li> <li>Types of statistical methods used in conjunction with PAT and process control</li> </ul>	<ul style="list-style-type: none"> <li>End-to-end value chain of biopharmaceuticals manufacturing</li> <li>Methods of formulating business cases for PAT implementation</li> <li>Benefits and costs of implementing PAT</li> <li>Methods of implementing PAT</li> <li>Constraints in implementing PAT</li> </ul>	<ul style="list-style-type: none"> <li>Technical requirements of PAT</li> <li>Methods of using PAT to conduct atline, online or inline measurements</li> <li>Risks and critical control points of biopharmaceuticals manufacturing processes</li> <li>Types of multivariate programs that compare quality and performance attributes</li> <li>Design features of PAT system interfaces</li> <li>Statistical and analytical methods</li> </ul>	
<b>Abilities</b>			<ul style="list-style-type: none"> <li>Conduct market analysis and research on PAT</li> <li>Monitor PAT outputs</li> <li>Validate PAT data</li> <li>Measure correlation and dependency between process variables</li> <li>Build linear regression models for analysis of PAT data</li> </ul>	<ul style="list-style-type: none"> <li>Project costs and business value of implementing PAT within the manufacturing facilities</li> <li>Evaluate operational feasibility of implementing PAT within the manufacturing facilities</li> </ul>	<ul style="list-style-type: none"> <li>Assess technical feasibility of introducing PAT</li> <li>Review market and feasibility analyses to select appropriate PAT</li> <li>Spearhead the introduction of PAT</li> <li>Develop PAT operating procedures and process maps</li> </ul>	

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			<ul style="list-style-type: none"> <li>Identify variables that relate to production efficiency and final product quality outcomes</li> </ul>	<ul style="list-style-type: none"> <li>Formulate business cases for implementation of selected analytical technologies in an atline, online or inline capacity</li> <li>Outline the benefits of each mode of implementation</li> <li>Guide operational deployment of PAT in the manufacturing plants</li> <li>Develop plans for process change following on from PAT findings</li> </ul>	<ul style="list-style-type: none"> <li>Define the performance parameters to be monitored and assessed</li> <li>Develop PAT system interfaces</li> <li>Evaluate regression model accuracy and model coefficient significance</li> <li>Direct analysis of product batches to define reference trajectories for product quality variables and review results</li> <li>Initiate interventions to address variables that relate to production efficiency and final product quality outcomes</li> </ul>	
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