

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

TSC Category	Process Development/Manufacturing Science and Technology					
TSC	Biological Product Introduction					
TSC Description	Facilitate the introduction of new biological products by designing manufacturing processes needed to achieve cost-effective production and meet design specifications					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
				BPM-PST-4002-1.1	BPM-PST-5002-1.1	BPM-PST-6002-1.1
				Develop manufacturing process steps and identify materials required for the introduction of new biologics products	Review manufacturing process plans to achieve requisite product quality and production requirements for new biologics products	Direct the introduction of manufacturing processes for new biologics products by aligning manufacturing plans with Research and Development (R&D) design specifications and sales forecasts
Knowledge				<ul style="list-style-type: none"> • Current Good Manufacturing Practices (CGMPs) related to biologics manufacturing • Principles of biochemistry • Principles of chemical engineering • Concepts of bioprocess and biologics technology • Principles of fluid and particle mechanics • Types and properties of materials used in biologics manufacturing • Types of cell culture and fermentation processes • Types of purification and filtration processes • Types and uses of equipment in biologics manufacturing • Use of mammalian cells and other advances in biologics manufacturing 	<ul style="list-style-type: none"> • Regulatory and other requirements related to new biologics product manufacturing • Detailed product specifications • Impact of product specifications on biologics manufacturing processes • Methods of developing manufacturing process flow maps • Methods of developing manufacturing plans • Methods of formulating new product trial and re-trial objectives • Criteria for analysing trial and re-trial results • Principles of risk and feasibility assessments 	<ul style="list-style-type: none"> • Principles of biochemistry • Concepts of bioprocess and biologics technology • Principles of fluid and particle mechanics • Interpretation of Research and Development (R&D) specifications and implications on manufacturing processes • Impact of introducing new biologics products on sales, revenue and other business priorities • Methods of evaluating manufacturing plans and process flow maps
Abilities				<ul style="list-style-type: none"> • Consolidate initial assessments of manufacturing requirements 	<ul style="list-style-type: none"> • Determine technical specifications, aesthetic and regulatory requirements, timelines, cost and other market 	<ul style="list-style-type: none"> • Assess manufacturability of product designs • Endorse business and infrastructural support

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				<ul style="list-style-type: none"> • Identify manufacturing constraints • Develop manufacturing process steps for cell culture, purification, filling and finishing of new biologics products • Detail components of manufacturing process flow maps • Identify equipment and materials for production • Record details of manufacturing plans, consultation and evaluation processes • Perform manufacturing trials 	<p>requirements of the new biologics products</p> <ul style="list-style-type: none"> • Review process equipment and materials suggestions • Evaluate technical, operational and financial viability to manufacture new biological products • Lead the design of manufacturing plans that reflects Current Good Manufacturing Practices (CGMPs), product specifications and other regulations • Conduct risk and feasibility assessments of the manufacturing plans • Design manufacturing trials and outline the objectives • Review trial and re-trial product quality results and compare with trial objectives • Present manufacturing plans to seek endorsement • Monitor implementation of manufacturing plans and transfer of processes into manufacturing facilities 	<p>viability to manufacture new biological products</p> <ul style="list-style-type: none"> • Evaluate manufacturing plans against Research and Development (R&D) design specifications and sales forecasts • Endorse material and equipment selections • Align complexity and resource requirements of manufacturing plans and processes with actual and projected business value of the biologics products • Establish implementation strategies to support technology transfer and deployment of new production processes • Establish methodologies for technology transfer and scale-up activities • Oversee technical transfer of processes into manufacturing facilities • Facilitate cross functional collaboration and activities to drive successful transition to full scale production
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