

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

TSC Category	Process Development/Manufacturing Science and Technology					
TSC	Pharmaceutical and Nutritional Product Introduction					
TSC Description	Develop manufacturing plans and processes for new pharmaceutical or nutritional products to achieve cost-effective production and Research and Development design specifications					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
				BPM-PST-4006-1.1	BPM-PST-5006-1.1	BPM-PST-6006-1.1
				Develop manufacturing process steps and identify materials required for the introduction of new pharmaceutical or nutritional products	Review manufacturing process plans to achieve requisite product quality and production requirements for new pharmaceutical or nutritional products	Align manufacturing plans for new pharmaceutical or nutritional products 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 pharmaceutical and nutritional product manufacturing • Principles of analytical chemistry • Principles of chemical engineering • Principles of fluid and particle mechanics • Types and properties of materials used in pharmaceutical and nutritional product manufacturing • Processes used to manufacture, blend and mix Active Pharmaceutical Ingredients (API) • Types of secondary manufacturing processes in pharmaceutical and nutritional product manufacturing • Types and functions of equipment used in pharmaceutical and 	<ul style="list-style-type: none"> • Regulatory and other requirements related to pharmaceutical and nutritional product manufacturing • Detailed product specifications • Impact of product specifications on pharmaceutical and nutritional product 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 analytical chemistry • Advanced principles of chemical engineering • Advanced principles of fluid and particle mechanics • Interpretation of Research and Development (R&D) specifications and implications on manufacturing processes • Impact of introducing new pharmaceutical or nutritional products on sales, revenue and other business priorities • Methods of evaluating manufacturing plans and process flow maps

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				<p>nutritional product manufacturing</p> <ul style="list-style-type: none"> • Types of manufacturing process design constraints • Components of manufacturing plans and process flow maps 		
Abilities				<ul style="list-style-type: none"> • Consolidate initial assessments of manufacturing requirements • Identify manufacturing constraints • Develop manufacturing process steps for API production, blending, filling and finishing of new pharmaceutical or nutritional 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 	<ul style="list-style-type: none"> • Determine technical specifications, aesthetic and regulatory requirements, timelines, cost and other market requirements of the new pharmaceutical or nutritional products • Review process equipment and material proposals • Evaluate technical, operational and financial viability to manufacture new pharmaceutical or nutritional products • Review the manufacturing process flow maps • 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 	<ul style="list-style-type: none"> • Assess manufacturability and completeness of product designs • Endorse business and infrastructural support viability to manufacture new pharmaceutical or nutritional products • Approve 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 with actual and projected business value of the 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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					<ul style="list-style-type: none">• Present manufacturing plans to seek endorsement• Monitor implementation of manufacturing plans and technical transfer of processes into manufacturing facilities	
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