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

TSC Category	Process Development/Manufacturing Science and Technology					
TSC	Manufacturing Process Design					
TSC Description	Design cost-efficient, robust and reliable manufacturing processes aligned with stakeholder expectations, business priorities and industry best practices					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
				BPM-PST-4005-1.1	**BPM-PST-5005-1.1**	**BPM-PST-6005-1.1**
				Develop biopharmaceuticals manufacturing processes guided by product requirements and Current Good Manufacturing Practices (CGMPs)	Formulate key drivers for process designs and recommendations to enhance manufacturing processes	Influence the innovative and progressive design of manufacturing processes that drive business value
Knowledge				• CGMPs • Key principles and methodologies in process designs • Principles of analytical chemistry and biochemistry • Process Flow Diagrams (PFD), plant layouts and other parts of process technical documents • Linkages among mechanical, hydraulic, pneumatic, electrical, control, computer and other systems and components • Range of manufacturing technologies, systems and infrastructure that underpin processes • Interdependencies among teams, work units, intra- and inter-organisational systems and the larger environments • Range of manufacturing processes in the biopharmaceuticals industry covering assembly, cleanroom and heat treatment processes • Types and procedures of process control • Indicators of process failures	• Key business imperatives for the plants' manufacturing processes • Industry best practices in manufacturing process designs • Methods of continuous manufacturing in a biopharmaceuticals context • Manufacturing process analysis and review • Factors to assess manufacturability of products • Fundamental process steps and considerations for manufacturing processes involving different materials • Types of process transformations to scale up production/operations • Costs associated with manufacturing process designs • Resource requirements calculation and implications of new process designs • Commissioning methods and requirements for manufacturing of new products	• Business impact of manufacturing processes changes and transformations • Industry and technological developments in manufacturing • Principles of process innovation

Abilities				• Design process flow maps • Propose process control points and boundaries of control parameters • Evaluate and incorporate suitable manufacturing techniques and technologies as part of the processes • Verify the availability of infrastructure underpinning the manufacturing processes • Develop manufacturing process plans and documentation • Define extreme conditions to test manufacturing process parameters and points of product failures • Conduct pilots of the manufacturing processes • Develop Standard Operating Procedures (SOPs) for production • Revise process documents to incorporate relevant changes and new manufacturing processes	• Establish process design parameters based on resources, budgets and regulatory considerations • Keep abreast of industry developments in new manufacturing processes • Identify key drivers and priorities for the plants' manufacturing processes • Identify opportunities to refine or redesign manufacturing processes to enhance the quality or efficiency of production • Identify opportunities to use continuous and flexible manufacturing facilities in order to optimise efficiency • Direct the design of manufacturing processes • Highlight the impact of different materials and their properties on design requirements of the manufacturing processes • Review the capabilities and limitations of manufacturing processes • Evaluate costs, production times and staffing requirements for selected manufacturing process designs against business value • Review process control points and Standard Operating Procedures (SOPs) for production	• Anticipate broader business implications of changing or introducing new manufacturing processes • Articulate business priorities to guide the formulation of manufacturing process design principles • Devise ways to embed innovation and multi-disciplinary technologies in manufacturing processes • Align manufacturing processes across the plants • Approve final manufacturing process designs for implementation