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

TSC Category	Process Development/Manufacturing Science and Technology					
TSC	Facility Design					
TSC Description	Design and integrate biopharmaceuticals manufacturing facilities to optimise operational efficiency and effectiveness					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
				BPM-PST-4003-1.1	**BPM-PST-5003-1.1**	
				Design facility layouts for biopharmaceuticals manufacturing plants	Optimise facility designs and integrate with organisational and operational strategies	
Knowledge				• Purposes of specific biopharmaceuticals manufacturing facilities • Broad range of facility designs • Types of biopharmaceuticals manufacturing processes • Applications of flexible systems and single-use technologies • Pros and cons of different facility designs • Processes to integrate new systems such as single-use technologies into current processes • Government and industry regulations for facility designs and layouts • Infrastructure and facilities in biopharmaceuticals manufacturing plants • Components and requirements of plants' layout blueprints or simulations • Measurements and indicators of process scalability	• Principles of process redesign and implementation • Principles and practices of process and layout optimisation • Methods of assessing cost effectiveness of flexible facilities and other infrastructure investments • Workplace health and safety regulations, and their implications on layout viability	
Abilities				• Identify key purposes and requirements of the	• Determine overall feasibility and business	

				biopharmaceuticals manufacturing facilities and their end users • Translate end user requirements into infrastructural and feature requirements of the plants • Design facility layouts for the plants • Incorporate design features that facilitate equipment mobility • Develop plant layout plans, blueprints and simulations • Develop hybrid design solutions of multiple facility designs • Evaluate product processing and process equipment options that enable flexible manufacturing practices • Evaluate viability of incorporating single-use equipment technologies and systems that facilitate processing speed and flexibility • Evaluate the scalability of plant processes and parts	value of adopting flexible facilities for plant operations • Review alignment of flexible facility designs with government and industry regulations • Endorse flexible facility designs to be adopted by the plants • Determine organisation's approaches to build new facilities or remodel existing buildings • Evaluate the costs, benefits and potential business impact of introducing various forms of single-use technologies • Establish robust single-use processes for the facilities • Determine optimal single-use technologies that maximise processing flexibility • Anticipate impact of changes to production processes on wider business operations • Endorse designs of production processes in alignment with the plants' facilities and layouts	