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

TSC Category	General Management					
TSC	Systems Thinking					
TSC Description	Integrate understanding of biopharmaceuticals manufacturing with interactions between components when developing manufacturing processes or overseeing manufacturing activities					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-GMT-2013-1.1	**BPM-GMT-3013-1.1**	**BPM-GMT-4013-1.1**	**BPM-GMT-5013-1.1**	
		Identify interdependencies within manufacturing processes and apply knowledge in day-to-day work	Identify how isolated interventions could impact biopharmaceutical products quality as a whole	Predict changes to processes and interdependencies over time	Formulate effective strategies targeting management of multi-disciplinary and interdependent manufacturing processes	
Knowledge		• Biopharmaceuticals manufacturing process and equipment • Systems thinking tools and methodologies • Application of systems thinking principles	• Biopharmaceutical manufacturing interventions • Manufacturing processes and equipment changes • Common process interdependence issues	• Business strategies and objectives • Market conditions • Emerging manufacturing trends and new technologies • Forecasting tools and methodologies	• Culture and change management • Strategies to manage process complexities and interdependencies • Troubleshooting and diagnostic methodologies for multi-disciplinary systems	
Abilities		• Recall the end-to-end biopharmaceuticals manufacturing processes to identify formal and informal process steps • Identify how individual and team actions may impact manufacturing results • Identify how different stages of the manufacturing processes can impact one another • Describe interdependencies within manufacturing processes • Apply a broader perspective to suggest improvements to be	• Frame current issues in the context of the end-to-end manufacturing processes to facilitate decision making • Interpret interdependencies within the manufacturing processes to support effective decisions regarding interventions and changes • Envision the big picture and how isolated areas impact processes as a whole • Identify potential domino effects or chain reactions caused by new process steps or decisions	• Forecast the long term business impact of proposed interventions and changes • Predict changes to processes and interdependencies over time as a result of operational needs and market constraints • Leverage interdependencies to suggest tweaks to interventions and changes for greater impact and more controlled outcomes	• Inspire culture and habit of broad, integrated systems thinking within the organisation • Anticipate wider organisational implications of changing or introducing new processes • Develop effective strategies targeting management of multi-disciplinary and interdependent manufacturing processes • Project the short and long term impact of interventions and changes • Diagnose manufacturing issues by evaluating a broad range of variables	

		made within own work area				