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

TSC Category	Engineering and Maintenance					
TSC	Automated Process Design					
TSC Description	Design processes that utilise automated manufacturing equipment and control systems					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-ENM-3003-1.1	**BPM-ENM-4003-1.1**	**BPM-ENM-5003-1.1**	**BPM-ENM-6003-1.1**
			Conduct research to support the introduction of automated manufacturing equipment and control systems	Design production processes that utilise automated manufacturing equipment and control systems	Drive the introduction of new production processes that utilise automated manufacturing equipment and control systems to enhance operational efficiency	Explore new applications of automated methods of manufacturing using expertise within the field to transform production workflows
Knowledge			• Types and features of automated equipment and control systems used in biopharmaceuticals manufacturing • Methods of producing production flow maps • Rejection parameters used for automated equipment • Current Good Manufacturing Practices (CGMPs)	• Types and functions of sensors used in production processes • Types of data outputs that can be obtained from using sensors • Methods of conducting feasibility studies for new automated equipment • Types of automated equipment simulation tools • Methods of constructing two-dimensional (2D) and three-dimensional (3D) technical drawings • Production process steps	• Operational targets for production processes • Financial costs of introducing automation to production processes • Methods of conducting return-on-investment (ROI) analyses	• Macro trends and their impact on biopharmaceutical manufacturing • Applications of emerging automation technologies • Impact of automation to biopharmaceuticals manufacturing operations • Principles of change management • Principles of risk management • Robotics and automation legislative requirements
Abilities			• Conduct research to compare manual processes with automation and identify implications on existing processes • Explore information on automated processes applied by competitors or industry leaders in the sector, or used in adjacent industries	• Identify production process steps that could be conducted using automated equipment • Determine control requirements of automated systems • Plan routes for mobile robots • Establish acceptance criteria for robot performance	• Review automation proposals for production processes against operational requirements • Evaluate the extent to which the new automated process complies with Current Good Manufacturing Practices (CGMPs) • Assess the cost and return on investment of	• Synthesise innovative developments in the biopharmaceutical manufacturing industry • Anticipate macro trends and their impact on speed, process or automation requirements in the biopharmaceutical manufacturing • Lead innovation in automation of production processes

			• Map production processes to new automated equipment • Set rejection parameters for out of control products for automated processes	• Define sensor and operational configuration to ensure control, measuring and feeding mechanisms will function appropriately • Assess feasibility of automating specific parts of the manufacturing processes • Implement new automated processes and adjust designs as necessary	automating production processes • Develop a report that evaluates whether the automated design meets functional requirements • Facilitate implementation of new automated processes	• Evaluate different automation approaches to select interventions that enhance precision and productivity • Develop organisational automation implementation strategies • Synergise the use of automation with new and existing production processes