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

TSC Category	Engineering and Maintenance					
TSC	Equipment Qualification					
TSC Description	Verify that biopharmaceuticals manufacturing equipment are installed, operate and perform as per expectations and requirements					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-ENM-3007-1.1	**BPM-ENM-4007-1.1**		
			Perform equipment qualification and validation activities to verify their conditions and performances	Establish equipment and facility qualification processes		
Knowledge			• Current Good Manufacturing Practices (CGMPs) and requirements for Equipment Qualification (EQ) requirements • Validation Master Plan (VMP) Installation Qualification (IQ), Performance Qualification (PQ) and Operational Qualification (OQ) procedures • Equipment specifications • Indicators of sub-optimal performance and quality issues • Validation reporting standards	• Optimal timing and frequency for equipment and qualification and validation • Manufacturing equipment design, installation, operation and performance requirements • Optimal equipment, conditions to meet process efficacy and product quality requirements • Impact of equipment and components on biopharmaceuticals product quality • Impact of equipment, changes on process efficacy or product quality • Regulatory requirements • Audit procedures		
Abilities			• Develop protocols and parameters for equipment qualification in line with the VMP • Determine suitable tools for qualifying and	• Develop a Validation Master Plan (VMP) for the qualification and validation of manufacturing equipment in the facility		

			validating manufacturing equipment • Perform equipment qualification and validation tests • Investigate deviations encountered to isolate causes • Recommend adjustments and repairs for equipment that do not meet the pre-specified criteria • Document validation results • Develop equipment qualification and validation reports	• Articulate objectives of and key indicators of successful equipment qualification and validation • Review protocol and parameters for equipment qualification • Specify the equipment, characteristics to be validated • Evaluate impact of process changes on qualification and validation efforts required • Determine the need for equipment and facility shut-down in order to conduct validation activities • Determine which equipment can be validated using automated technologies • Lead investigations into failed qualification tests • Review validation reports to identify areas for improvement		