

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

TSC Category	Engineering and Maintenance					
TSC	Installation and Assembly					
TSC Description	Install equipment and system components by evaluating product specifications and manufacturers' recommendations and aligning them with the needs of the manufacturing facility					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-ENM-2009-1.1	BPM-ENM-3009-1.1	BPM-ENM-4009-1.1	BPM-ENM-5009-1.1	
		Execute installation and assembly of equipment and system components	Determine installation and assembly requirements for specific equipment and system components, produce technical installation blueprints and oversee executions	Assess the suitability of equipment and system components to be installed and provide technical expertise to support the development of technical installation plans	Develop installation and assembly plans for new equipment and systems, ensure sufficient resources and align with operational requirements	
Knowledge		<ul style="list-style-type: none"> Types of installation and assembly techniques Applications of installation and assembly techniques Types and functions of installation and assembly tools Operation of tools and equipment for executing installation and assembly methods Procedures of calibrating tools Interpretation of installation plans Interdependencies with other equipment and systems Limitations of different installation and assembly techniques Safety precautions to be observed during installation 	<ul style="list-style-type: none"> Interpretation of technical specification sheets Methods of identifying installation and assembly requirements Methods of estimating installation cost and resource requirements Methods of operating Computer-Aided Design (CAD) software Methods of developing an installation and assembly plan and sketches Health and Safety Procedures relevant to insulation and assembly works Safety requirements for new equipment and systems 	<ul style="list-style-type: none"> Detailed procedures of executing installation and assembly techniques Manufacturers' recommendations and limitations Best practices and optimal features of installation and assembly plan designs 	<ul style="list-style-type: none"> Key priorities and objectives in biopharmaceutical manufacturing plant Resource requirements of overall installation and assembly works Factors that influence the achievement of installation objectives Strategic thinking and its application to installation of new equipment and systems Responsibilities of the engineering and maintenance team Contingency measures for installation delays Methods of managing the vendors and contractors involved in installation and assembly Methods of assessing a return on investment on the installation costs of new equipment and systems Methods to improve the cost effectiveness and 	

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					quality of installation works	
Abilities		<ul style="list-style-type: none"> • Interpret work requirements from sketches, specifications and/or blueprints • Prepare appropriate tools, equipment and materials for installation and assembly • Take appropriate measurements based on equipment's specifications • Install machine parts, equipment, and other devices according to specifications • Align connections with other equipment and systems as required • Coordinate installation and assembly work performed by vendors • Calibrate tools and installation equipment as per manufacturers' instructions • Document the installation processes in accordance with organisational procedures • Comply with Quality and Health, Safety and Environment (HSE) procedures when carrying out installation and assembly works 	<ul style="list-style-type: none"> • Develop basic installation and connection blueprints using computer-assisted engineering or design software • Verify installation and assembly works are conducted with accordance to required standards • Check equipment and systems are connected according to technical specifications • Outline safety procedures to adhere to during installation works and ensure compliance • Perform installations of new or non-standard equipment • Update documentation for installation and assembly works 	<ul style="list-style-type: none"> • Develop engineering specifications and detailed drawings or flowcharts to guide installation works • Review installation instructions and structural blueprints to ascertain specifications, procedures, and objectives are met • Direct the installation of equipment and systems across the manufacturing facility • Review records of all installation works conducted • Ensure safety features meet regulatory requirements • Commission new equipment and systems for full-scale production 	<ul style="list-style-type: none"> • Liaise with key stakeholders to determine objectives of major installation works • Predict installation and assembly resource factors • Review budget requests for installation works • Develop an installation and assembly plan for major works including timeline and resource requirements and manufacturing launch plan • Provide installation plans and resource requirements with other relevant metrics to senior management for approval • Verify achievement of key performance indicators of all installation and assembly works • Manage major installation and assembly works to ensure timeline and cost requirements are met • Manage vendors and contractors to ensure contractual requirements are met • Liaise with other departments to ensure the installation and assembly plans are aligned with manufacturing needs 	

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					<ul style="list-style-type: none">• Direct commissioning and launch activities	
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