

<b>SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING</b> <b>SKILLS MAP – ENGINEERING AND MAINTENANCE PRINCIPAL/SENIOR ENGINEER</b>		
<b>Sector</b>	Biopharmaceuticals Manufacturing	
<b>Track</b>	Engineering and Maintenance	
<b>Occupation</b>	Engineer	
<b>Job Role</b>	Engineering and Maintenance Principal/Senior Engineer	
<b>Job Role Description</b>	<p>The Engineering and Maintenance Principal/Senior Engineer applies advanced engineering principles and techniques to troubleshoot complex engineering problems encountered within the manufacturing facility and provides expert technical advice to guide the installation and maintenance of equipment and systems. He/She is expected to lead the technical cross-collaboration with the Process Development/Manufacturing Science and Technology (PD/MSAT) department in order to identify appropriate biopharmaceuticals manufacturing equipment and optimise their functionalities. The Engineering and Maintenance Principal/Senior Engineer leads manufacturing equipment and systems innovation projects by guiding feasibility assessments and tests on new technologies. He is expected to review and approve solutions and initiatives to optimise machine availability while managing energy and utility use. He sets parameters for equipment qualification and validation in line with biopharmaceuticals manufacturing regulatory requirements. The Principal/Engineer must ensure compliance with Standard Operating Procedures (SOPs), Health, Safety and Environment (HSE) regulations and Current Good Manufacturing Practices (CGMPs) within his purview.</p> <p>The Engineering and Maintenance Principal/Engineer carries the responsibility of the in-house technical expert. He should possess a deep passion for analysing and resolving multifaceted engineering problems and be able to apply advanced critical and analytical thinking skills to deal with immediate situations. He should have a developmental and amiable approach in his interactions working as part of a team while guiding and mentoring others. He must also be able to communicate engineering concepts in a manner that will be understood by others within and beyond the team.</p>	
<b>Critical Work Functions and Key Tasks</b>	<b>Critical Work Functions</b>	<b>Key Tasks</b>
	Install equipment and systems	Approve all installations and assembly works prior to use for full-scale productions
		Guide the development of engineering plans to ensure technical drawings are produced in an optimal manner
		Review installations and assembly documentations periodically to ensure compliance with organisational procedures
		Review recommendations and approve equipment to be installed
Maintain equipment and systems	Formulate predictive maintenance techniques for the manufacturing facility to predict when maintenance should be performed	

		Approve recommended repair works for major equipment and system failures
		Draw insights and trends from testing, maintenance and repair records that may impact manufacturing operations and quality
		Drive the Maintenance Excellence Programme (MEP) for the manufacturing facility
		Evaluate root cause analysis reports of major equipment and system failure, and develop potential solutions
		Provide expert technical guidance on maintenance requirements of new or complex equipment and systems
		Review and approve maintenance and spare parts plans and Standard Operating Procedures (SOPs)
		Review and approve plans, guiding procedures, and parameters for equipment and systems testing and repair
	Manage energy resources and utilities	Anticipate changes to energy resources and utilities usage requirements for the plant
		Evaluate technical viability of initiatives to optimise energy and utility efficiencies
		Provide expert technical advice to resolve significant or non-standard lapses or disruptions to energy resources and utilities supplies
		Review and approve requirements for energy resource and utilities supply and operational standards
	Innovate equipment, systems and controls	Approve proposed modifications to automated equipment, systems and controls
		Commission feasibility assessments for new automated equipment, systems and controls
		Conduct training on the operations and maintenance of new automated equipment, systems and controls
		Establish technical guidelines for the calibrations and alignments of robot motors, sensors and encoders
		Optimise the motion, functions, and routes of robots and other equipment and system components
		Oversee test-runs of new processes involving automated equipment, systems and controls
		Provide expert technical guidance on troubleshooting automated equipment malfunctions and system bugs

	Validate equipment	Oversee equipment qualification and validation activities in the facility		
		Review and approve protocol and parameters for equipment qualification and validation		
		Review equipment qualification and validation reports to identify areas for improvement		
<b>Skills &amp; Competencies</b>	<b>Technical Skills &amp; Competencies</b>		<b>Generic Skills &amp; Competencies (Top 5)</b>	
	Automated Equipment and Control Systems Configuration	Level 5	Communication	Advanced
	Automated Process Control	Level 4	Decision Making	Intermediate
	Automated Process Design	Level 5	Interpersonal Skills	Advanced
	Big Data Analysis	Level 4	Problem Solving	Advanced
	Change Management	Level 4	Teamwork	Intermediate
	Computer Systems Validation	Level 5		
	Conflict Resolution	Level 4		
	Continuous Improvement	Level 5		
	Engineering Drawing	Level 4		
	Equipment and Systems Repair	Level 5		
	Equipment Qualification	Level 4		
	Facility Maintenance	Level 4		
	Flexible Facilities Implementation	Level 5		
	Good Manufacturing Practices Implementation	Level 5		
	Green Manufacturing Design and Implementation	Level 4		
	Health, Safety and Environment Procedures Implementation	Level 4		
	Innovation Management	Level 5		
	Installation and Assembly	Level 4		
	Maintenance Strategy Development	Level 5		
	Manufacturing Equipment Operation and Control	Level 5		
	Manufacturing Systems Operation and Control	Level 5		
	Preventive Maintenance	Level 5		
	Process Analytical Technology Implementation	Level 5		
Process Monitoring	Level 5			
Process Optimisation	Level 4			

	Systems Thinking	Level 5	
	Technical Presentation	Level 5	
	Test Planning	Level 5	
<b>Programme Listing</b>	For a list of Training Programmes available for the Biopharmaceuticals Manufacturing sector, please visit: <a href="http://www.skillsfuture.sg/skills-framework/biopharmmmfg">www.skillsfuture.sg/skills-framework/biopharmmmfg</a>		

The information contained in this document serves as a guide.